'A comparison of the femAssist and Reliance devices in the management of urinary incontinence in women'

Boos, Kelvin Patrick William

"TITLE"

"A comparison of the FemAssist and Reliance devices in the management of urinary incontinence in women".

DEGREE OF DOCTOR OF MEDICINE

KELVIN PATRICK WILLIAM BOOS

TEXT CUT OFF IN ORIGINAL

ABSTRACT

AIMS

Study the efficacy, safety, acceptability and impact on quality of life (QoL) of the Reliance and FemAssist continence devices in the management of women with genuine stress incontinence (GSI).

METHODS

In a prospective trial, subjects with reasonable eyesight, mobility and manual dexterity were eligible. Exclusion criteria included recurrent urinary tract infection, diabetes, pregnancy or haematuria. Assessments were made at baseline, one, three and six months.

"Bothersome" foreign body sensation was noted and assessment of comfort, ease of placement and protection afforded with device utilisation were ranked.

Outcome measures included the number of incontinence episodes (IEPD), continence pads used (recorded on a urinary diary) and amount of leakage on a pad test (PWT). The Kings Health and Short Form 36 questionnaires were used to evaluate QoL.

Safety was judged by urinalysis, urine cultures, physical examination and reported adverse events. Womens experiences of device use were recorded.

RESULTS

53 women were selectively allocated to the FemAssist and 48 to the Reliance. Subjects were well matched and the mean age was 50.2 years (range 30-77).

Foreign body sensation was similar, but satisfaction (comfort, easy placement) was better with the FemAssist device, albeit required greater user skill. QoL scores significantly improved within both groups. Problems experienced were few with no serious adverse events.

The Reliance achieved significantly greater reduction in PWT gains but other outcome measures were comparable.

	Reliance		*FemAssist*	
Outcome measures	**Start**	**6 months**	**Start**	**6 months**
IEPD	5.21	1.32	5.0	1
Pads used	10.5	3.45	11.1	4.35
PWT (g/hr)	32.6	1.3	28.7	3.6
Dry (subjective)		19 (39.6%)		20 (37.7%)
Improved		12 (25%)		18 (34%)
UTI		10.4%		11.3%

	Lost to follow-up	**Inhibition**	**Urethritis**	**Poor Efficacy**
FemAssist **(n=17)**	10	0	1	6
Reliance **(n=17)**	8	3	4	2

CONCLUSION

Devices are beneficial and acceptable methods to contain urinary incontinence, confer improved QoL and should be recommended to women with GSI.

TABLE OF CONTENTS **Page numbers**

PREFACE

INTRODUCTION

The preface will act as a guide or template to the dissertation, describing briefly the composition of each chapter. In presenting this material I have drawn upon my own practical experience as well as the clinical experience and teaching of the subject of urogynaecology and urodynamics gained as a result of working with Linda Cardozo and other research fellows who have shaped and modified my approach to the subject.

As an extension of the preface, ***THE COMPONENTS OF THE CONTINENCE SERVICE AT KINGS COLLEGE HOSPITAL AND THE SETTING FOR THIS THESIS*** are described separately. The expectation is that the reader will understand why the research was performed and be confident that it took place in a unit dedicated to the care of incontinent women of all ages with exactly the criteria for a system able to fully manage the patient. This also helped to ensure that the thesis and my training were fully supervised by Prof. Cardozo. It brings together a description of the present structure, organisational framework and method of functioning of the wide range of services available to the incontinent woman at the Urogynaecology Unit where this research was carried out. In undertaking such a description it is necessary to strike a balance between over-complexity and undue simplicity. So to preserve clarity only the broad aspects are presented and are in general terms correct.

In chapter one entitled ***EPIDEMIOLOGY AND CLASSIFICATION OF URINARY INCONTINENCE*** I deal with the concept of the cause of genuine stress incontinence. Outlined is the way in which the nature and frequency of urinary incontinence can vary within different groups of the population from one period of time to another. Examining the pattern of disease in populations in this way provides the starting point for studies which encourage service or treatment initiatives.

To understand and appreciate the impact of continence devices on women with GSI, one must first describe its prevalence and the natural history of the condition. One must understand the pathophysiology of the condition and its consequences on the individual and society as a whole.

Chapter two summarises the modern ***TREATMENT OF FEMALE GENUINE STRESS INCONTINENCE*** in a manner which emphasises the merit and validity of the study relevant to the way patients are managed. In order to observe the

consequences of the interventions used to contain urinary leakage in this study, it is important to examine other known methods to gauge their effects and uses.

Chapter three describes the ***QUALITY OF LIFE AND IMPACT OF INCONTINENCE*** in women. Research has until recently concentrated on the prevalence, aetiology, diagnosis and management of urinary incontinence and relatively little us known about the effects of this chronic condition or indeed its management on quality of life and psychosocial functioning. Because urinary incontinence is a quality of life issue, the patient must be allowed to express her preference of options and the degree of intervention.

Chapter four provides a ***REVIEW OF THE LITERATURE ON CONTINENCE DEVICES AND AIDS***. Clinical experience is too restricted a perspective to use to draw conclusions about how successful is individual treatment of urinary incontinence using continence aids. An accurate picture of the safety and efficacy of devices can be obtained from data collected and analysed in other studies. This may act as a helpful reference to test the clinical value of these aids to continence, and permit interpretation of the results of this trial in relation to the findings of other authors.

In chapter five I have introduced the ***URODYNAMIC ASSESSMENT*** and main steps to be taken in diagnosing the health problems of the population of women studied with urinary symptoms. In an attempt to demystify it, I have put special emphasis on providing simple descriptions and definitions of the concepts involved and explained the urodynamic tests available. This also serves in part to outline the precise clinical and laboratory techniques used to obtain the data.

The chapter on ***PATIENTS AND METHODS*** includes the study design, formulation of the aims of the study, stating the null hypothesis and defined targets, the study population and the selection of a suitable sampling frame. As the study units were patients at a hospital with a particular disease (genuine stress incontinence), how representative are these patients? Could the fact that these are patients attending a Urogynaecology unit somehow make them unrepresentative? I.e. specialise in more severe cases. Does geographic location or condition have an effect? What was the target population compared with the study population? These issues will be

discussed. After the study units were selected, how the study was conducted is summarised. The inclusion and exclusion criteria for entry into the study are stated as well as the criteria for the disease or condition being measured. The intervention or continence devices are also described.

Next, in chapter seven, it is essential to define the ***OUTCOME MEASURES*** or objectives of the programme of continence device intervention against which outcomes are to be measured and to select an appropriate study design. Scientific evaluation of the outcome of therapeutic interventions in patients is not possible without appraisal before and after the intervention. Outcome is usually defined in terms of the achievement of or failure to achieve desired goals or objectives. This definition is common to both outcome and need and the same measures are often appropriate to each. In preparing the basis of this thesis I addressed the question of what to measure, from whose perspective and according to which criteria in addition to selecting the appropriate measures.

Comments are made on how suitable is the chosen method for the purpose of the investigation, what is the power of the chosen measure to detect differences and how reproducible is the method in general terms. Outcome measurements should be based on repeated investigations performed under identical circumstances before and after the therapeutic intervention. The test/retest variation of the reporting centre are given in order to make evaluations of the results possible to interpret and evaluate by others. It is important to state the normal values in healthy women. One can then make inferences on how differences might be explained. A change can be defined as a value outside the test/re-test interval and an improvement as a change towards normality.

There are several reasons why subjective indicators are of value in the assessment of the effects of these devices. It is perceived, and not necessarily actual situations which result in the adoption of health related behaviour, including the demand for continence aids. It is also important for clinicians to be aware of and to understand the beliefs and perceptions of the subjects whom they are treating. Only then can continence programs be made appropriate and relevant to perceived needs

Chapter eight, the ***MEASURES OF THE CONSEQUENCES OF TREATMENT*** stresses that the appropriate methods of analysis are determined by the study design

so as to allow sound meaningful interpretation of the results, and not just increase the quantity of data from the combination of clinical observations and standard urodynamic measurements. Specific statistical methods are indicated and used to analyse the data to allow inferences to be made. Each method required a certain assumption of the data but are appropriate to the study design and scale of measurements.

Chapter Nine provides a deliberation on the ***ASSESSMENT OF DEVICE SAFETY***. The safety of each device was evaluated by urinalysis and urine culture, physical examination and any spontaneously reported adverse events. There is an explanation of what each means and detailed information in particular on the conditions of cystitis and urethritis, capillary fragility, petechial haemorrhages and bruising.

Chapter ten depicts the ***OBJECTIVE RESULTS FOR THE RELIANCE AND FEMASSIST DEVICES.*** In describing the results, I have tried to avoid merely cataloguing them, but have commented on their distinctiveness and highlighted the deficiencies. Throughout, the reader is made aware of the strengths and limitations of the data so as to avoid hasty or inaccurate interpretation of them and the practical difficulties involved in pursuing the goals of the study.

Chapter eleven illustrates the ***RESULTS OF QUALITY OF LIFE ASSESSMENT.*** The value of appropriate designs and analysis of quality of life studies will be lost if one does not present the results clearly and concisely. Graphical presentations can be used to accomplish this objective and communicate the overall summaries of results. These can convey results in a manner than allows the reader to individually balance the importance of baseline versus post treatment differences among the two treatment groups.

Chapter twelve records the ***SIDE EFFECTS EXPERIENCED BY THE RELIANCE AND FEMASSIST GROUPS*** as a consequence of device utilisation.

Chapter thirteen displays the completeness of the data and ***ANALYSIS OF DROPOUTS AND NON-RESPONDERS***. Some patients have missing data and if large then the credibility of the results should be questioned. In some studies any data

such as outliers are discarded. I did not discard any proportion of the data that does not support the research hypothesis maintaining scientific objectivity.

Chapter fourteen presents the logic of the ***CONCLUSION AND FUTURE RESEARCH***. Do they make sense? Can one reasonably use the results of this study to guide the treatment of other patients?

COMPONENTS OF THE CONTINENCE SERVICE AT KINGS COLLEGE HOSPITAL AND THE SETTING FOR THIS THESIS

Education and training in Urogynaecology is still undergoing considerable evolution throughout the world. The first formalisation of Urogynaecology as a subspecialty occurred in Australia followed by the United Kingdom [1]. The latter has two certified training programs which has produced one certified graduate to date. In the USA, Urogynaecology is now a formal subject required to be taught in post-graduate residency training programs. The department of urogynaecology and urodynamics at Kings College Hospital is a certified centre where the training of research fellows mirrors that of the Urogynaecology subspecialty trainee.

KINGS COLLEGE HOSPITAL

The work contained in this thesis was undertaken at King's College Hospital, London, in the Department of Urogynaecology from August 1995 until February 1998. The setting at Kings College Hospital is a hospital based consultant-led continence service headed by Professor Linda Cardozo the designated co-ordinating consultant. The Urodynamic Unit at King's College Hospital is a tertiary referral centre established by Professor Cardozo in 1979 and has continued to expand since that time. Not only does the clinic benefit from direct consultant input, but it also employs four full time research registrars (of which I was one), a full time urodynamic nurse and contracts sessions from the District Continence Advisor.

In 1991, the Department of Health [2] issued guidelines which suggested that the key components of an effective continence service should include the following:

- Active, enthusiastic consultant with general manager involvement.
- Continence advisors with management and teaching skills and a moderate caseload to maintain their clinical skills.
- A computer to store patient information.
- Active publicity work and sympathetic, knowledgeable telephone advice
- A separate budget.

Since the problem of incontinence involves many disciplines, Prof. Cardozo has arranged a formal structure to co-ordinate these and provides a readily accessible and well-recognised service. There is a defined method of entry for patients referred by general practitioners, nurses and hospital staff. There is ready access to appropriate diagnostic facilities and the full complement of modern urodynamic investigations, including ambulatory urodynamics, is available for patient assessment.

There is access to medical and surgical consultants with a special interest in incontinence within the hospital and outside. There is also access to nurses and physiotherapists with special training in treatment modalities for incontinence. Provision is made to ensure a direct role of a specialist continence advisor in the education of the public and associated carers in the maintenance of continence. With the hospital team, the continence advisor maintains a policy concerning the purchasing and supply of containment materials and equipment in the community and in the hospital proper. She also deploys other continence advisors and specially trained link nurses in the community. These structures and policies are subject to regular audit and quality assurance systems. This is achieved with the help of a designated manager and a multidisciplinary steering group with a financial budget to provide staff, their training and support services and containment materials and equipment. The service has an agreed and clearly written policy which is available to all relevant health professionals and purchasers within the hospital trust.

Regular hospital based continence clinics are conducted involving the consultant, research fellows, specialist registrars, the nurse specialist and continence advisor. A permanent office accepting telephone enquiries is available at all times during the day. Prof. Cardozo has cultivated educational programme and audit procedures

around this continence service. With the particular advantages of access to diagnostic facilities, this programme has made available many opportunities to develop medical research. Within this agenda, simple cases are diagnosed and managed appropriately by the general practitioner with referral to a community continence advisor for supplies of continence products if required. More complex cases are referred to the hospital based continence clinic.

In the latter months of 1992 the UCARE clinic (Urodynamic Clinic for the Assessment and Review of the Elderly) was established. This clinic, co-ordinated by the Urodynamic Nurse Specialist and the District Continence Advisor, was designed to cope with the increasing number of elderly women referred for urodynamic assessment, for whom it was felt that videourodynamics may have been unnecessary and additional unhurried time was needed for complete assessment. The clinic offers a full nursing assessment as well as uroflometry, cystometry and urethral pressure profilometry without radiological imaging.

All referrals are made directly to and reviewed by the consultant and then allocated to one of three types of clinics; elderly or disabled patients with an uncomplicated history are seen in the UCARE clinic; routine urodynamic referrals are booked into one of the urodynamic clinics held four times a week and run by the research fellows. Complex tertiary referrals are seen by the consultant in the gynaecology clinic prior to videourodynamics performed in the consultant clinic. All complex cases and all UCARE patients are reviewed by Prof. Cardozo and the team at a fortnightly video review meeting.

As a tertiary referral centre many complex referrals are seen each year. The majority of patients however are primary or secondary referrals directly from general practitioners or from consultants at other regional hospitals as well as our own gynaecology clinic.

A major criticism of many studies is that they are a reflection solely of the indigenous population in the locality of the study. As a tertiary referral centre situated in South London, the unit attracts referrals from a very large multi-racial, urban and suburban catchment area. Our referrals are therefore likely to mitigate against this form of

selection bias, although such biases can never by discounted completely unless studies are conducted on a multi-centre national or international basis.

A large proportion of women requires surgery in the form of urinary continence procedures and pelvic floor reconstruction. Operating lists are provided to accommodate this service and the research fellows are trained to carry out such operations until competent.

The International Continence Society (ICS) was founded in 1970 to develop a multidisciplinary scientific approach to the management of continence. It is a multidisciplinary body of scientists and clinicians which first established a committee for the standardisation of terminology of lower urinary tract dysfunction in 1973. These standards have been revised and extended to keep pace with improvements in urodynamic techniques and have been adopted world wide to provide a common framework for clinical and research work in the field of urinary incontinence. Prof. Cardozo is closely involved with the activity and function of the society and abides by the standards set to ensure reliable high quality urodynamic practice.

SUMMARY

Why do we need this service?

- Incontinence of urine in women is very common
- An average health authority of 250,000 population can expect to have 10,000 adults who are incontinent and many more who are unknown to the health services
- In England, the Department of Health has reviewed continence services and the National Health Service Management Executive have identified continence services as a priority in its policies and planning guidelines for 1994-95 [3 4].

Jolleys and Wilson have highlighted the lack of medical training in continence care at undergraduate and post-graduate levels in the U.K [5]. It is obvious that political interest in the problem continues to grow, with a variety of clinical and service projects receiving Department of Health funding.

References

---

[1] Ostergard D. Education and training in Urogynaecology. Int Urogynecol J 1997;8(1):56.

[2] Department of Health. Community Service Division. An agenda for action on continence services. London: Department of Health 1991.

[3] Department of Health, 1991. An agenda for action on continence services. ML (91)1. Department of Health, London.

[4] NHS Management Executive, 1993. Priorities and Planning Guidance 1994-1995. EL(93)54. Department of Health, Leeds.

[5] Jolleys J, Wilson J. Urinary incontinence: GP's lack of confidence. B M J 1993;306:1344.

CHAPTER ONE

EPIDEMIOLOGY AND CLASSIFICATION OF URINARY INCONTINENCE

INTRODUCTION

Urinary incontinence is a common problem affecting two to three million women in the UK. In many chronic diseases such as urinary incontinence, complete recovery does not occur. The incidence of GSI is an estimate of the risk of developing the disease and hence is of value mainly to those concerned with searching for the cause or determinants of the disease. Knowledge of the prevalence of GSI is of particular value in planning health services, since it indicates the amount of incontinence requiring care.

Epidemiological studies have attempted to measure the size of the incontinent population and to isolate risk factors common to incontinence sufferers. Studies are often limited by the reluctance of women to admit to incontinence and consequently the true extent of this distressing condition is probably underestimated.

PREVALENCE STUDIES

Epidemiological studies are fraught with methodological problems and biases which include the sample population chosen, the definition of incontinence adopted and the common problems of under reporting of embarrassing conditions. Prevalence surveys are usually conducted as personal interviews, postal surveys or by telephone and it is important to recognise the limitations of each of these methods when interpreting data. Two previous studies on the prevalence of urinary incontinence have found that for every case of recognised incontinence (incontinence known to a member of the primary care team) there are about 20 unrecognised cases [1 2].

In a large general practice study, O'Brien et al (1991) showed a prevalence of 16.4% of women aged 35-64 reporting regular urinary incontinence and also confirmed the great reluctance of patients to bring their incontinence problems to the attention of members of the primary care team [3]. However, among those who had discussed their problems, only 20% had been assessed within the past year and 30% had never had any form of assessment. The variation between reports on the prevalence of incontinence is probably due to the variety of definitions used with different time scales, such as ever incontinent, incontinent in the last two months, incontinence requiring the use of pads, a change of pants or underclothes. Reports also vary depending on the population surveyed, such as those at home, community dwelling,

institutionalised and the frail elderly as well as the method of information gathering. Brocklehurst (1993) in the analysis of a MORI poll found that in all, 14% of women were or had been incontinent [4]. 9.3% of women were incontinent in the previous year and 7.5% in the previous two months (Table 1.1). In this study, 60% of incontinent subjects were concerned or worried about their problem and 34% of women felt it affected their lifestyle considerably. Treatment was often prescribed without clinical examination or without a diagnosis being made. Fewer than 5% of those who consulted a doctor were referred to a nurse or continence advisor.

Prevalence of incontinence in women				
Age	**N**	**Ever**	**Previous Year**	**Previous 2Months**
30-49	921	100(10.9)	66(7.2)	50(5.4)
50-59	363	56(15.4)	33(9.1)	23(6.3)
>/= 60	840	141(16.8)	98(11.7)	86(10.2)
TOTAL	2124	297(14.0)	197(9.3)	159(7.5)

Table 1.1 Prevalence of incontinence in women of different age groups and at different periods of their lives. The ages are in years and the percentages in brackets. {Brocklehurst (1993)}

Yarnell et al 1981 in a well-constructed epidemiological study found that 3 – 7% of women in the general population complained of significant urinary incontinence [5]. The severity of incontinence has been assessed in a number of ways but most often with reference to the frequency of leakage, varying from 'daily' to 'weekly' to 'once or twice a month'. Wyman et al (1990) assessed the subjective impact and frequency or urinary leakage using the 'Incontinence Impact Questionnaire' and a urinary diary [6]. They found only a modest correlation between the two. These findings suggest that severity cannot be measured in terms of the frequency of incontinence alone and other severity criteria must be addressed.

Incontinence is likely to be under reported, rather than over reported and therefore higher figures are likely to be more accurate. The phenomenon whereby only a proportion of patients make contact with health services and in particular hospital services is often referred to as the "tip of the iceberg". The processes which lead to this are plentiful: shame and embarrassment; an assumption that nothing can be done; lack of publicity for services to name but a few.

Prevalence of any urinary incontinence	
Study	**Prevalence**
Milne et al (1972)	
65+ year olds	34%
Thomas et al (1980)	
25 – 64 year olds	18%
65 + year olds	23%
Yarnell et al (1981)	
25 – 64 years olds	46%
65 + year olds	49%
Vetter et al (1981)	
61 year olds	14%
Diolno et al (MESA) study (1986)	
65 + year olds	30%

Table 1.2 The prevalence of 'any incontinence' amongst women residing independently in the community.

THE PREVALENCE OF SEVERE URINARY INCONTINENCE

Although prevalence studies have not attempted to validate the measures of severity, estimates of 'severe incontinence' are more consistent than those for 'any loss' (Table 1.3). They range from 3% to 11% with the majority between 4% and 6% and are therefore considerably lower than those of any urinary leakage. Studies have estimated that almost 50% of nursing home residents are incontinent of urine [7].

Prevalence of severe urinary incontinence	
Study	**Prevalence**
Milne et al (1972)	5%
Yarnell et al (1979)	11%
Thomas et al (1980)	10%
Vetter et al (1981)	5%
Campbell et al (1985)	3%
Diokno et al (MESA) study (1986)	4%

Table 1.3 The prevalence of severe urinary incontinence.

RISK FACTORS FOR URINARY INCONTINENCE

The human female pelvis as a result of containing the abdominopelvic organs and resisting the forces of gravity and raised intra-abdominal pressure must confront the problems which quadruped mammals are not prone to. Parturition traumatises the

supportive muscles, ligaments, connective tissue, fascia and nerves within the pelvic cavity so intimately involved in the processes of urinary and faecal continence and genital support. Added to this are the effects of ageing and oestrogen deficiency.

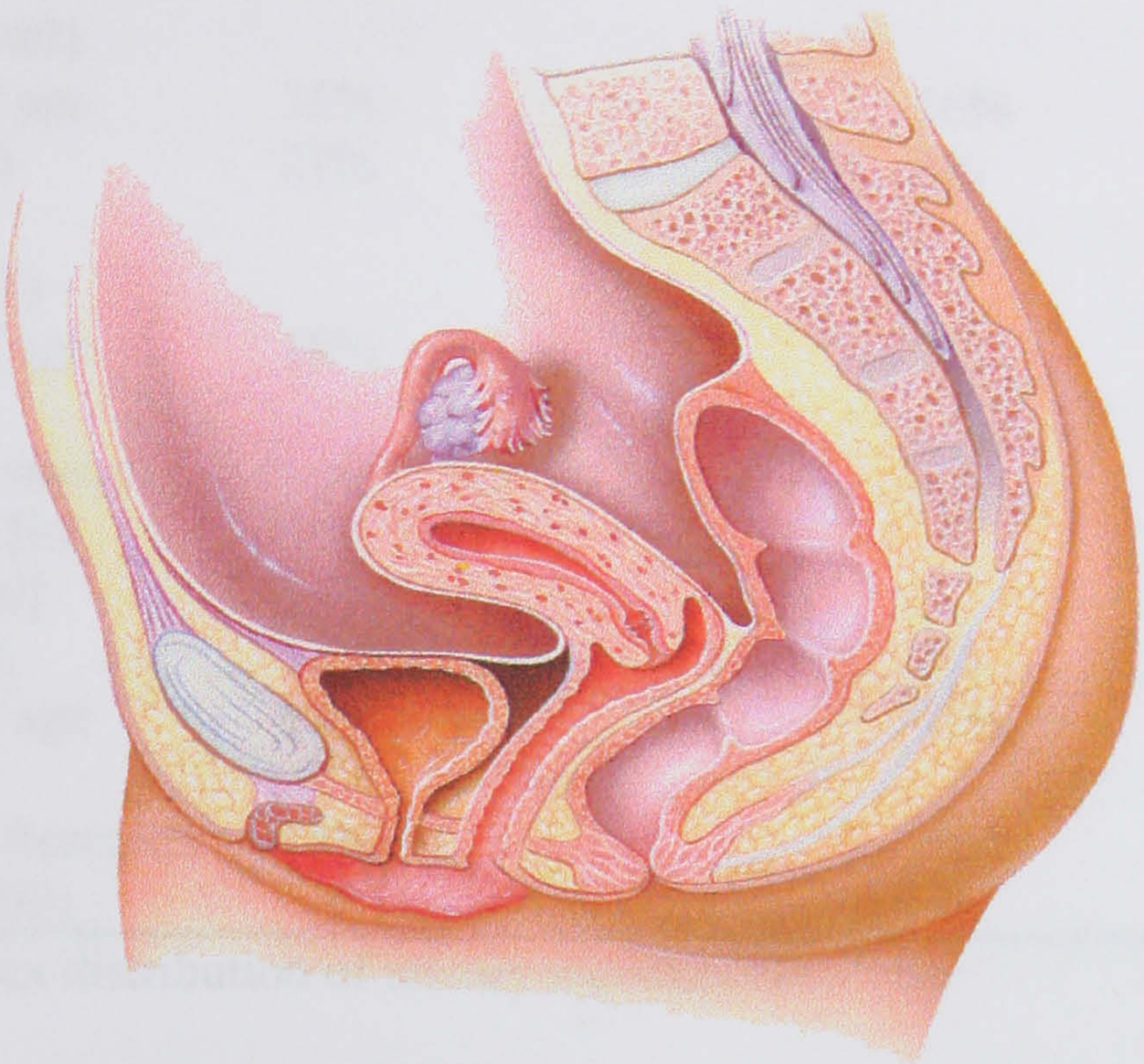


Figure 1.1 The female pelvis.

Race, smoking, constipation, obesity and gynaecological surgery have all been studied as potential aetiological factors.

Age and Gender

Urinary incontinence is commoner amongst women than men and its prevalence increases with age [8 9] (Table 1.4). Many elderly women actually consider their urinary symptoms to be a normal part of the ageing process rather than a manifestation of disease [10]. Malone Lee (1994) has shown that elderly women have a reduced flow rate, an increased post void urinary residual, a higher end filling cystometric pressure (and maximum filling pressure), reduced bladder capacity and lower maximum voiding pressures [11].

Gender distribution of urinary incontinence		
Study	**Prevalence**	
	Female	**Male**
Varnell et al (1979)		
Over 65 years of age	17%	11%
Thomas et al (1980)		
Over 65 years of age	31%	16%
25 – 64 years old	27%	5%
Vetter et al (1981)		
Over 65 years of age	18%	7%
Michegan Generations follow up(1987) [In Herzog et al 1990]		
23 – 62 year olds	12%	2%
Over 63 years of age	23%	11%
Market Opinion Research International (1990)	14%	7%

Table 1.4 The sex distribution of urinary incontinence.

Additional causes of incontinence in the elderly are illustrated in table 1.5.

Additional causes of incontinence in the elderly
• Urinary tract infection
• Faecal impaction
• Decreased mobility
• Acute illness / acute confusional state
• Drugs (e.g. diuretics, hypnotics)
• Change of environment (e.g. hospitalisation)
• Heart failure
• Oestrogen deficiency
• Metabolic abnormalities
• Endocrine abnormalities (e.g. Diabetes)
• Renal problems
• Dementia

Table 1.5 Causes of incontinence in the elderly.

Hormonal status

In England and Wales there are approximately 10 million climacteric or postmenopausal women and therefore 1 in 5 of the population is potentially at risk of the symptoms of urogenital oestrogen deficiency [12]. At approximately 40 years of age

the frequency of ovulation declines, initiating a period of waning ovarian function - the climacteric. This results sequentially in reduced ovulation, menstrual irregularities, the menopause and finally generalised atrophy of all oestrogen - sensitive tissues.

The female genital and urinary tracts develop in close proximity, both arising from the embryological urogenital sinus. Studies have shown that the adult female urogenital tissues are oestrogen sensitive and oestrogen and progesterone receptors have been identified in the human urethra, bladder, vagina, and pelvic floor, irrespective of hormonal status [13] [14]. At present the importance of oestrogen deficiency compared to that of the ageing process per se is unclear, although it is likely to be of significance in the maintenance, if not the genesis, or urinary problems in post menopausal women. In their large postal survey of almost 10,000 British women, Thomas et al (1980) showed that the prevalence of incontinence increased with age, but not specifically at the time of the menopause; whereas Iosif and Bekassey (1984) found that the prevalence of stress incontinence reached a peak at the age of 50 years and declined thereafter [15].

An analysis of both urinary symptoms and urodynamic findings amongst climacteric women was performed at the Dulwich Menopause Clinic [16]. 228 women referred for various climacteric complaints completed a detailed urinary symptom questionnaire and underwent urodynamic investigations comprising pad testing, uroflometry, videocystourethrography, cystometry and urethral pressure profilometry. Symptoms of stress incontinence occurred in over 50% of women and of urge incontinence in 26%. Only 60% of women had normal urodynamic investigations. Despite the common finding of urinary symptoms and urodynamic abnormalities, no correlation was seen with the time or duration of the menopause.

Race

Racial differences in the prevalence of urinary incontinence are difficult to quantify as cultural factors alter the perception and presentation of urinary complaints. Although few epidemiological data are available, incontinence appears to be least common amongst Chinese, Eskimo and coloured women [17]. Bump (1992) compared clinical and urodynamic parameters of 54 black and 146 white women referred for evaluation of incontinence (154) and severe prolapse (46) [18]. He found the proportion of black

and Caucasian patients with severe prolapse to be the same, but showed the causes of urinary incontinence to be significantly different between the two groups (Table 1.6).

Urinary incontinence and racial origin		
		Race
Variable	**Black**	**White**
Symptoms of incontinence		
Stress incontinence	7%	31%
Urge incontinence	56%	28%
Mixed incontinence	37%	41%
Cause of incontinence		
Genuine stress incontinence	27%	61%
Detrusor instability	56	28%
Mixed incontinence	17%	11%

Table 1.6 The cause of incontinence and racial origin. (Bump 1992).

Pregnancy and childbirth

Pregnant women commonly complain of stress incontinence and this has been attributed to the high level of progesterone during pregnancy. Van Geelen et al (1982) however performed urethral pressure profilometry on 43 pregnant women and found no change in the maximum urethral closure pressure despite high levels of 17 hydroxyprogesterone [19]. Also, displacement from the "normal" position may occur as a result of an increasingly gravid uterus. The pelvis and lower genitourinary tract undergo profound changes that do not completely revert to the nulliparous state. This occurs for a variety of reasons including the hormonal effects, pressure from the gravid uterus and circumstances surrounding delivery. The effect of peptide hormones such as relaxin also plays a role in connective tissue metabolism during pregnancy [20]. This hormone attains highest plasma levels during pregnancy and has been shown to induce collagen remodelling and consequent softening of the tissues of the birth canal [21 22].

The prevalence of stress incontinence has been reported in a number of studies. Stanton (1980) reported a change from 0% prior to first pregnancy to a peak of 41% at 38 weeks in multiparous women [23]. Cutner et al (1992) found a similar prevalence of stress incontinence, but it must be stressed that the patient groups were not

homogeneous [24]. Iosif (1981) in a retrospective postal survey of 1400 women found an overall incidence of 22% of stress incontinence [25] (Table 1.7).

Incidence of stress incontinence relative to pregnancy (Iosif 1981)		
Time of onset	**Percentage of symptoms**	**Percentage of total population**
Prior to pregnancy	**8.5%**	**2%**
Permanent onset during pregnancy	**23%**	**5%**
Temporary in pregnancy	**50%**	**11%**
Postnatal onset	**19%**	**4%**

Table 1.7 Incidence of stress incontinence relative to pregnancy.

Viktrup et al (1992) followed 305 women longitudinally [26]. They reported similar figures of 4% stress incontinence prior to delivery, increasing to 32% during pregnancy and 7% postnatally (Table 1.8). The authors correlated the development of postnatal urinary symptoms to birth weight, episiotomy and length of second stage of labour. They also found that caesarean section conferred some protection against developing incontinence. At three months postpartum all obstetric correlation's had disappeared in the women who remained symptomatic. At one year postpartum only 3% of women admitted to urinary stress incontinence.

Onset of stress incontinence (Viktrup 1992)	
Time of onset	
Prior to pregnancy	4%
During pregnancy	32%
Postnatally	7%

Table 1.8 Onset of stress incontinence relative to pregnancy.

All these studies suggest that symptoms of stress incontinence are common during pregnancy, but the majority are temporary during the confinement, resolving postnatally.

Birthweight

Krue et al (1997) investigated birth weight in 194 women who delivered vaginally and found an increased incidence of both antenatal and postnatal symptoms for women having a baby of greater than four kilograms [27] (Table 1.9).

Incidence of symptoms and birth weight over 4 kg (Krue 1997)		
Symptoms of stress Incontinence	**Fetal weight over 4 Kg**	**Fetal weight Under 4 Kg**
Antenatal	10%	6.9%
Postnatal	34%	30.6%

Table 1.9 Incidence of symptoms of stress incontinence and birth weight over 4 kg.

The same group also reported an increased incidence of stress incontinence in women with a body mass index of over 30 $Kg/_M2$

Instrumental delivery is often cited as a factor in the development of urinary symptoms. In England the assisted delivery rate among primiparous women varies from 10-24% [28]. Given the relatively frequent use of these instruments there is a paucity of objective evidence to support the claim of their involvement in the aetiology of stress incontinence. Wilson et al (1996) in their epidemiological study of 1800 women three months after delivery found no difference in the incidence of incontinence between women having a forceps delivery or a normal delivery (odds' ratio 0.8-1.6) [29]. Jackson et al (1997) also showed little difference in incidence of incontinence regardless of the use of epidural anaesthesia or instrumental delivery [30].

The ethnic differences quoted in non-pregnant populations have also been described relating to pregnancy and childbirth. Burgio et al (1996) studied 523 women and found an incidence of stress incontinence of 62.5% in white women and 46.4% in blacks [31].

Caesarean section is often thought to protect against damage and pelvic floor dysfunction. In a recent survey 31% of female obstetricians described caesarean section as their personal preferred method of delivery, with 80% citing fear of pelvic floor damage as the reason [32]. Wilson et al (1996) reported that caesarean section reduced the prevalence of urinary incontinence from 27% in women delivering vaginally to 5% after caesarean section [29]. There was little difference in this study between elective and emergency caesareans. The protective effect seemed to lessen

with subsequent operative deliveries and three caesarean sections conferred no advantage over vaginal births.

Pelvic floor and nerve damage

During parturition the pudendal nerve which supplies the pelvic floor is vulnerable to damage with disruption to the terminal branches supplying the pelvic floor, bladder and urethra. The pelvic floor itself may be marred by tearing during birth or by cutting at the time of an episiotomy. Also the use forceps increases the diameter of the head during delivery potentially increasing trauma to the birth canal.

Sampselle (1990) showed in a small study of 20 women that pelvic floor contractility and strength correlate inversely with the development of symptoms after childbirth [33]. This suggests that pelvic floor exercises antenatally may protect against the development of stress incontinence. Genuine stress incontinence cannot however be explained wholly by the effects of vaginal delivery and urinary incontinence does not appear to be a invariable consequence of childbirth.

Connective tissue factors

Research has suggested that the collagen of women with prolapse and stress incontinence may be different from that of women who do not develop these conditions. Landon and Smith (1989) found that abdominal wall collagen was less stiff in women with stress incontinence than in continent controls and Sayer et al (1990) showed that the collagen of pubocervical fascia of stress incontinent women was weak due to an abnormal cross linking of collagen fibrils [34 35]. The composition of collagen in women with stress incontinence may therefore be abnormal and predispose them to urethral sphincter incompetence.

Type I collagen forms thick, strong fibre units whereas, Type II collagen forms thin, weak and isolated fibres. Keane et al (1992) performed periurethral biopsies on 30 nuiliparous women with genuine stress incontinence [36]. They found a decrease in Type I compared to Type II collagen, as well as a reduction in the total amount of collagen in GSI sufferers compared to continent controls.

Smoking, obesity and chronic constipation

Any condition resulting in a chronically elevated intra-abdominal pressure is likely to increase the risk of developing or exacerbating stress incontinence. Obesity, chronic constipation and smoking have been suggested as important predisposing factors in the causation of genuine stress incontinence although insufficient data exists to refute or confirm these assumptions [37 38 39].

Hysterectomy and urinary incontinence

Urinary incontinence may be a complication of hysterectomy. There are many potential mechanisms of incontinence following hysterectomy, namely derangement of the bladder supports, pelvic nerve damage and oestrogen deficiency resulting from concomitant oophorectomy [40 41].

Prolapse and Anterior repair

Genital prolapse and urinary incontinence are common conditions and it is therefore not surprising to find both in some women. Rosenzwieg et al (1992) have shown almost 60% of women with severe genital prolapse and no symptoms of incontinence to have underlying urinary incontinence revealed by urodynamic testing [42]. Thomas et al (1978) and Meyhoff et al (1985) reported stress incontinence in 19% and 25% of continent women following anterior colporrhaphy for prolapse and Iosif (1979) reported a decrease in urethral closure pressure following similar surgery [43 44 45].

CLASSIFICATION OF LOWER URINARY TRACT DYSFUNCTION

The standardisation committee of the International Continence Society (ICS) have provided a common classification of lower urinary tract dysfunction (Tables 1.10 and 1.11). The lower urinary tract comprises the bladder and urethra. Each has two functions, the bladder to store and void and the urethra to control and convey urine.

Together they form a single functional unit under complex neurological control and dysfunction of one or both can result in urinary incontinence.

CLASSIFICATION OF LOWER URINARY TRACT DYSFUNCTION	
Storage phase	
Bladder	
Detrusor activity;	Normal Overactive (Detrusor instability) Hyperreflexia
Bladder sensation;	Normal Increased (hypersensitive) Reduced (hyposensitive) Absent
Bladder capacity	Normal adult >/= 400 mls
Bladder compliance	Rise for filled volume </=500mls (normally </= 15cm H_2O pressure)
Urethra	
Urethral function	Normal Urethral sphincter Incompetence

Table 1.10 Lower urinary tract dysfunction during the storage phase of the micturition cycle.

CLASSIFICATION OF LOWER URINARY TRACT DYSFUNCTION	
Voiding phase	
Bladder	
Detrusor	Normal Underactive (Hypotonic bladder) Acontractile (Atonic bladder)
Urethra	Obstructive (mechanical; urethral stricture) Overactive; (detrusor sphincter dyssynergia)

Table 1.11 Lower urinary tract dysfunction during the voiding phase of the micturition cycle.

Stress incontinence is the commonest symptom with which women present to a gynaecologist and indicates the involuntary loss of urine during physical exertion. Urge incontinence is the involuntary loss of urine associated with a strong desire to

void. Unconscious incontinence is urinary leakage in the absence of urgency and without conscious recognition of the urine loss. Enuresis denotes any involuntary loss of urine, although it is usually used to describe incontinence during sleep (nocturnal enuresis). Post micturition dribble and continuous incontinence are other symptomatic forms of urinary leakage often associated with prolapse, a urethral diverticulum or fistula. Major causes of urinary incontinence are listed in table 1.12.

Major causes of urinary incontinence
▪ Genuine stress incontinence (GSI)
▪ Detrusor instability (DI) (Detrusor hyperreflexia)
▪ Overflow incontinence
▪ Fistulae (vesicovaginal, uterovaginal, urethrovaginal)
▪ Congenital (e.g. epispadias / ectopic ureter)
▪ Urethral diverticulae
▪ Temporary (e.g. urinary tract infection, faecal impaction, drugs)
▪ Functional (e.g. immobility)

Table 1.12 The causes of urinary incontinence

GENUINE STRESS INCONTINENCE

The term "stress incontinence" was coined by Sir Eardley Holland in 1928 and refers to the loss of urine during physical effort. Genuine stress incontinence, detrusor instability and overflow incontinence are the most common causes of urinary incontinence in women. Genuine stress incontinence is the commonest cause of urinary incontinence in women and can be due to weakness in any component of the urethral sphincter mechanism (Table 1.13)[46]. Genuine stress incontinence accounts for 50% of cases and detrusor instability 40%. Overflow incontinence accounts for most of the remaining 10% [47].

Mechanisms for urethral competence	
Supporting structures	Pubourethral ligaments
	Pubovesical ligaments
	Rhabdosphincter
	Collagen and fascia
	Intact nervous system
Intrinsic sphincter mechanism	Urethral vascularity
	(smooth muscle)
Extrinsic sphincter mechanism	Pelvic floor musculature

Table 1.13 The mechanisms involved in urethral competence.

The contents of the female abdominal and pelvic cavities depend on the pelvic floor for support. The urethra, vagina and rectum pass through this structure, so its role is not solely supportive, but it must augment urinary and faecal continence as well as accommodating parturition. The pelvic floor supports are not rigid and unyielding but consist of smooth and striated muscle, collagen, fibrous and connective tissue capable of movement or dynamic changes under conditions of stress. Urinary continence is thought to be achieved by an intact urethral sphincter mechanism as well as the adjacent structures of the pelvic floor [48 49 50] (Figure 1.2).

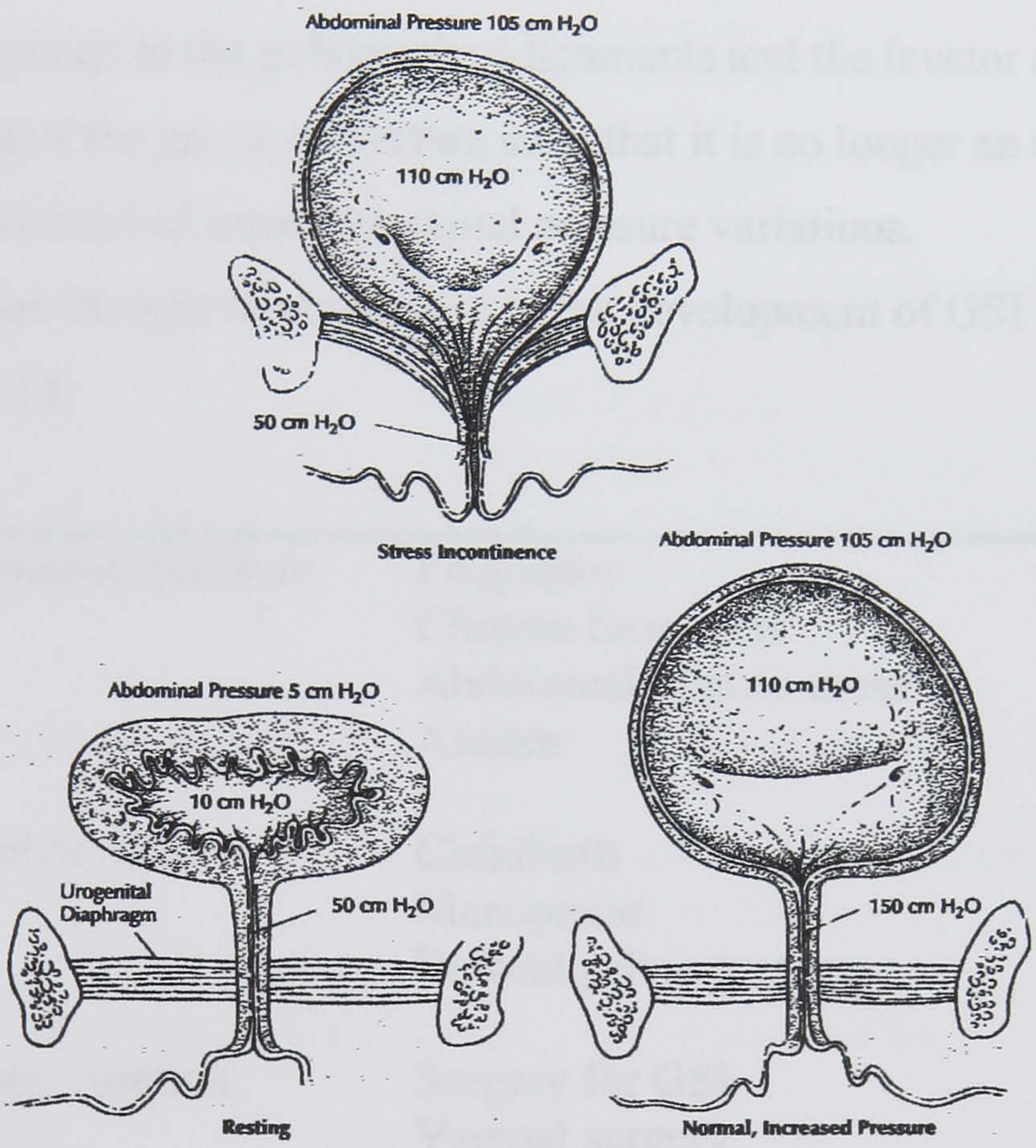


Figure 1.2 Mechanisms of urinary continence.

The work of Enhorning provides strong evidence as to the mechanism of bladder neck and urethral closure during physical effort in continent women [51]. With the urethra correctly positioned in the pressure zone of the abdominal cavity, raised intra abdominal pressure is transmitted equally to the bladder and urethra, closing off the bladder neck and preventing leakage of urine. In addition, structures outside the lower urinary tract aid continence and are referred to as the extrinsic continence mechanism [52 53 54 55]. This mechanism assists both passive and active bladder neck closure in women, by virtue of the structural supports of the urethra and the stability

accorded by the muscles of the pelvic floor and bony pelvis[56 57]. The urogenital hiatus, which is bordered by the medial edge of the levator ani muscle, consists of the pubococcygeus and ileococcygeus which are attached to and have a major role in upholding the pelvic viscera and lower urogenital tract [58]. Damage to the levator ani contributes to urogenital prolapse. In addition, activity in the striated muscles of the levator ani is thought to constrict the urogenital hiatus and assist in active closure of the structures which pass through it. Thus, both periurethral support structures and the levator ani muscle function to sustain the pelvic viscera as well as contributing to resting urethral pressure and urethral closure during raised intra-abdominal pressure [59].

Weakness or damage to the pubourethral ligaments and the levator ani muscles results in descent of the proximal urethra such that it is no longer an intra-abdominal organ under the control of intra-abdominal pressure variations.

Various factors are thought to predispose to the development of GSI and these are shown in table 1.14.

Raised intra-abdominal pressure	Pregnancy Chronic bronchitis Abdominal / pelvic mass Ascites
Damage to the pelvic floor	Childbirth Menopause Radical pelvic surgery
Scarred "drainpipe" urethra	Surgery for GSI Vaginal surgery Urethral dilatation Recurrent urethritis Radiotherapy

Table 1.14 Predisposing factors in the pathophysiology of GSI.

DETRUSOR INSTABILITY

The unstable detrusor is one that is shown objectively to contract, spontaneously or on provocation, during the filling phase of cystometry whilst the patient is attempting to inhibit micturition. These contractions may result in the leakage of urine. The incidence increases with age and DI is the commonest cause of urinary incontinence

in the elderly [11]. Detrusor contractions may be either phasic, or systolic where they mimic the normal voiding reflex or the bladder wall may demonstrate low compliance. Women usually present with multiple symptoms; most commonly urgency, urge incontinence, frequency and nocturia. A list of the common causes of frequency and urgency of micturition is shown in table 1.15.

The pathophysiology of detrusor instability is poorly understood and an underlying cause for the condition is rarely found. In the majority of cases therefore, the term 'idiopathic detrusor instability' is used. Detrusor instability can arise de novo following surgery for genuine stress incontinence.

Causes of frequency and urgency of micturition in women

Type	Example
Gynaecological/Urological	Detrusor instability
	Urinary tract infection
	Inflammation (e.g. interstitial cystitis)
	Atrophy (menopause)
	Fibrosis (radiation)
	Urethral pathology (e.g. urethral syndrome)
	Intravesical lesion (e.g. calculus)
	External pressure (e.g. pelvic mass/fibroids)
	Pregnancy
Medical/Psychological	Drugs (e.g. diuretics)
	Diabetes
	Neurological disease (e.g. multiple sclerosis)
	Excessive fluid intake
	Habit

Table 1.15 The causes of frequency and urgency of micturition

Any neurological condition which interrupts the cortical inhibition of reflex detrusor contractions will result in unstable detrusor contractions. This is known as detrusor hyperreflexia and causes include multiple sclerosis and spinal cord lesions.

LOW COMPLIANCE

In this condition there is an excessive rise in detrusor pressure associated with bladder filling. There are a variety of causes which include recurrent urinary tract infection, radiotherapy, radical pelvic surgery and pelvic masses. These patients are often symptomatically the same as those with detrusor instability (table 1.16).

Types of detrusor instability	
Idiopathic	
Low compliance	
Neurological	Spinal cord injury
	Multiple sclerosis
	Diabetic neuropathy
Outflow obstruction	
Psychosomatic	
Post surgical	

Table 1.16 The types of detrusor instability

OVERFLOW INCONTINENCE

Overflow incontinence is a condition in which the bladder becomes a large flaccid bag with little or no detrusor activity. Occasionally where there is chronic outflow obstruction the bladder becomes small and trabeculated due to fibrosis but again there is little or no detrusor activity. The woman fails to void and the bladder merely leaks each time it becomes full. In addition, due to the very small functional bladder capacity, she may develop frequency of micturition and recurrent lower and indeed upper urinary tract infections.

Fistulae secondary to obstetric trauma are a common cause of incontinence in developing countries. In the developed world, fistulae are usually secondary to gynaecological surgery although they are fortunately rare.

References

[1] Thomas T, Plymat K, Blannin J, Meade T. Prevalence of urinary incontinence. BMJ 1980;281:1234-5.

[2] Feneley R, Shepherd A, Powell P, Blannin J. Urinary incontinence: prevalence and needs. Br J Urol 1979;51:493-6.

[3] O'Brien J, Austin M, Sethi P, O'Boyle P. Urinary incontinence: prevalence, need for treatment and effectiveness of intervention by nurse. BMJ, 1991:303:1308-12.

[4] Brocklehurst J. Urinary incontinence in the community – analysis of a MORI poll. BMJ 1993;306:832-4.

[5] Yarnell J, Voyle G, Richards S, Stephenson T. The prevalence and severity of urinary incontinence in women. J Epidemiol Community Health 1981;35:71-4.

[6] Wyman J.F., Harkins S.W., Fanti J.A. Psychosocial impact of urinary incontinence in the community dwelling population. J AM Geriatr Soc 1990; 38: 282-288.

[7]Ouslander J.G., Hepps K., Raz S., Su H.L. Genitourinary dysfunction in an elderly outpatient population. J Am Ger Soc 1986 ; 34, 507-514.

[8] Thomas T.M., Plymat K.R., Blannin J., Meade T.W. Prevalence of urinary incontinence. Br Med J. 1980; 281: 1243-1 245.

[9] Vetter N.J., Jones D.A., Victor C.R. Urinary incontinence in the elderly at home. Lancet 1981; 2: 1275.

[10] Svanborg A. The gerontological and geriatric population study in Gbteborg, Sweden. Acta Med Scand, 1977; Suppi 611, 1-37.

[11] Malone Lee J. Lower urinary tract function in late life. In Handbook of Neurourology ed D.Rushton Marcel Dekker. New York. 1994 349-368.

[12] Central Statistics Office. Annual abstract of statistics, no 127. London: HMSO,1991.

[13] Cardozo LD. Role of oestrogens in the treatment of female urinary incontinence. JAGS 1990; 38: 326-328.

[14] Blakeman P, Hilton P, Bulmer J. Mapping oestrogen and progesterone receptors throughout the female lower urinary tract. Neurourology and Urodynamics 1996; 15(4): 324-325.

[15] Iosif C, Bekassey Z. Prevalence of genito-urinary symptoms in the later menopause. Acta Obstet Gynecol Scand, 1984; 63: 257-260.

[16] Versi E., Cardozo, L.D. Estrogens and lower urinary tract function. In Studd JWW, and Whitehead MI, (eds) The Menopause pp76-84, Blackwell Scientific publications 1988.

[17] Zacharin R. "A Chinese anatomy" the pelvic supporting tissues of the Chinese and Occidental female compared and contrasted. Aust NZ J Obstet Gynecol, 1977); 17:1.

[18] Bump R.C., Sugarman H.J., Fanti J.A., MeClish D.K. (1992) Obesity and lower urinary tract function in women. Effects of surgically induced weight loss. Am J Obstet Gynecol 1992; 167 (2) 392-397

[19] Van Geelen J. M., Lemmens W.A,J.G., Eskes T. K.A. 13., Martin 1. B. Jr. (1 982). The urethral pressure profile in pregnancy and delivery in healthy nulliparous women. Am J Obstet Gynaecol 1982, 144, 636-649.

[20]Bell RJ, Eddie LW, Lester AR, Wood EC, Johnston PD, Niall HD. Relaxin in human pregnancy serum measured with an homologious radioimmunoassay. Obstet Gynecol 1987;69: 585-9.

[21] Bani D. Relaxin: A pleiotropic hormone. Gen Pharmacol 1997;28: 13-22.

[22] Landon CR, Crofts CE, Smith ARB, Trowbridge EA. Mechanical properties of fascia during pregnancy: a possible factor for the development of stress incontinence of urine. Contemp Rev Obstet Gynecol 1990; 2:40-46.

[23]Stanton SL, Kerr-Wilson R, Harris GV. The incidence of urological symptoms in normal pregnancy. Br J Obstet Gynaecol 1980; 87:897-900.

[24] Cutner A, Carey A, Cardozo LD. Lower urinary tract symptoms in early pregnancy. J Obst Gynaecol 1992; 12:75-78.

[25] Iosif S. Stress incontinence during pregnancy and in puerperium. Int J Gynaecol Obstet 1981; 19(1):13-20.

[26] Viktrup L, Lose G, Rolff M, Barfoed K. The symptom of stress incontinence caused by pregnancy or delivery in primips. Obstet Gynecol 1992; 79(6):945-9.

[27] Krue S, Jensen H, Aggar AO, Rasmussen KL. The influence of infant birth weight on post partum stress incontinence in obese women. Arch Gynecol Obstet 1997; 259(3): 143-5.

[28] Drife JO, Choice and instrumental delivery. Br J Obstet Gynaecol. 1996; 103:608-611.

[29] Wilson PD, Herbison RM, Herbison GP. Obstetric practice and the prevalence of urinary incontinence three months after delivery Br J Obstet Gynaecol 1996; 103(2):154-61.

[30] Jackson S, Barry C, Shepherd A, Abrams P. Management of delivery in primiparous women: effect on subsequent urinary incontinence. Neurourol Urodynam 1997; 16(5): 387-8.

[31] Burgio KL, Locher JL, Zyczynski H, Hardin JM, Singh K. Urinary incontinence during pregnancy in a racially mixed group: characteristics and predisposing factors. Int Urogynecol J. Pelvic Floor Dysfunct 1996; 7(2):69-73.

[32] Al-Mufti R, McCarthy A, Fisk NN. Obstetricians personal choice and mode of delivery. Lancet 1996; 347:544.

[33] Sampselle CM. Changes in pelvic muscle strength and stress urinary incontinence associated with childbirth. J Obstet Gynecol Neonatal Nurs 1990; 19(5):371-7.

[34]Landon C.R., Smith A.R. Biomechanical properties of connective tissue in women with stress incontinence of urine. Neurourol Urodynam 1989. 8: 369-370

[35]Sayer T.R., Dixon J.S., Hosker G.L. Warrell D.W. (1990) A study of paraurethral connective tissue in women with stress incontinence of urine. Neurourol and Urodynam. 1990; 9: 319-320.

[36] Keane D. P., Sims T.J., Bailey A.J., Abrams P. Analysis of pelvic floor electromyography and collagen status in pre-menopausal nuiliparous females with genuine stress incontinence. Neurourol Urodynam 1992; 1 (4) 308- 309.

[37]Dwyer P.L., Lee E.T.C., Hay D.M. Obesity and urinary incontinence in women. Br J Obstet Gynaecol 1988. 95: 91.

[38]Bump R.C., Sugarman H.J., Fanti J.A., MeClish D.K. Obesity and lower urinary tract function in women. Effects of surgically induced weight loss. Am J Obstet Gynecol 1992; 167 (2) 392-397

[39]Bump R.C., MeClish D. K. Cigarette smoking and urinary incontinence in women. Am J Obstet Gynaecol 1992. 1 67: 12-13.

[40] Kikku P. Supravaginal uterine amputation versus hysterectomy with reference to subjective bladder symptoms and incontinence. Acta Obstet Gynecol Scand, 1985; 64: 375-379.

[41]Parys B.T. Lower urinary tract dysfunction after total hysterectomy. lnt Urogynaecol J. 1992; 1 2: 108-111.

[42]Rosenzweig B.A., Pushkin S., Biumenfeld D., Bhatia N. N. Prevalence of abnormal urodynamic test results in continent women with severe genitourinary prolapse. Obstet Gynecol, 1992; 79: 539-542.

[43] Thomas T.M., Fischer A.M., Walsh J.M. et al. Urinary incontinence before and after pelvic floor surgery. Vill International Continence Society meeting. Manchester. 1978; 163-166. Pergamon Press, Oxford.

[44] Meyhoff H.H., de Nully M.B., Oleson K.P., Lindahl F. The effects of vaginal repair on anterior bladder suspension defects. Obstet Gynecol Scand 1985 64: 433-435.

[45] Iosif C, Ulmstein U. Urodynamic studies of women with prolapse and stress incontinence before and after surgical repair. Obstet Gynecol 1979;101:1433-1437.(1979

[46] Drife J, Hilton P, Stanton S. (eds). Micturition. London: Springer Verlag, 1990.

[47] Shaw R, Souther W, Stanton S (eds). Gynaecology. Edinburgh: Churchill Livingstone, 1992.

[48] DeLancey JOL. Structural support of the urethra as it relates to stress incontinence: the hammock hypothesis. Am J Obstet Gynecol 1994; 170: 1713-1723.

[49] Cherry-DA, Rothenberger-DA. Pelvic floor physiology. Surg-Clin-North-Am 1988; 68(6): 1217-30.

[50] Leadbetter-GW. Internal urethrotomy in girls and its impact on the urethral intrinsic and extrinsic continence mechanisms. J-Urol. 1988; 139(1) 142-3

[51] Enhorning G. Simultaneous recording of intravesical and intra urethral pressure. Acta Chir Scand 1961; 27: 61-68.

[52] Gosling-JA. The structure of the female lower urinary tract and pelvic floor. Urol-Clin-North-Am. 1985; 12(2): 207-14.

[53] Kessler R, Constantinou CE. Internal urethrotomy in girls and its impact on the urethral intrinsic and extrinsic continence mechanisms. J Urol 1986; 136(6): 1248-53

[54] DeLancey JOL. Structural aspects of the extrinsic continence mechanism. Obstet-Gynecol 1988; 72(3) : 296-301.

[55] Reid-RE, Berman-SM, Laor-E, Tolia-BM, Schweizerhof-SP. Continence mechanisms following transphincteric urethroplasty. Eur-Urol 1988; 15(1-2): 66-8.

[56] Oelrich TM. The striated urogenital sphincter muscle in the female. Anat Rec 1983; 205(2): 223-32.

[57] Koelbl H, Strassegger H, Riss P, Gruber H. Morphologic and functional aspects of pelvic floor muscles in patients with pelvic relaxation and genuine stress incontinence. Obstet Gynecol 1989; 74: 789 - 793.

[58] Richardson AC, DeLancey JOL. Anatomy of genital support. In: Benson JT, editor. Female Pelvic Floor Disorders, Investigation and Management, New York, USA: Norton Medical Books, 1992: 19-26.

[59] DeLancey JOL, Kim K-J, Ashton-Miller JA, Strohbehn K. Relative contributions of resting urethral pressure and transmission ratios in determining pressure equalisation. Neurourol Urodynam 1996; 15 (4): 301-302.

CHAPTER TWO

THE TREATMENT OF
FEMELE GENUINE STRESS INCONTINENCE

THE TREATMENT OF
FEMALE GENUINE STRESS INCONTINENCE

All currently available treatment modalities in addition to continence devices were available to patients treated in the unit except for major reconstructive urological procedures and implantation of artificial urinary sphincters. As it is important to understand the methods of treatment in order to follow the outcome of the women, this chapter of my thesis reviews both the conservative and surgical treatment of female genuine stress incontinence.

CONSERVATIVE MANAGEMENT OF GSI

The conservative management of incontinence generally refers to a broad range of non-surgical therapies which are easy, inexpensive, and readily available. They have few complications and do not compromise future surgery. Conservative management is the first line of treatment of female urinary incontinence but the overall approach to the individual depends upon the outcome of thorough evaluation. An assessment should be made of the woman's mental state and her ability for self-care. Home circumstances should be assessed for factors which may contribute to urinary incontinence such as, inappropriate furniture heights (bed, chair, toilet), excessive distance to toilet, poor lighting as well as cool temperatures. If mobility is restricted, moving to a bedroom closer to the toilet or providing a bedside commode or rails at the toilet may correct functional incontinence. Apart from specific treatment modalities there are many simple measures that can improve or resolve incontinence (Table 2.1).

There are many causes of urinary incontinence in the elderly and many individuals may have more than one reason for their incontinence. Atrophy of the pelvic floor muscles can lead to poor sphincter tone and compound stress incontinence. Many diseases (stroke, diabetes and urinary tract infections) which become more common with advancing years may also cause continence problems. Other acute problems may result in a temporary loss of continence as a result of general debility or illness.

Treatment depends on the needs and expectations of the woman and she must be counselled with regard to the efficacy of the treatment and possible side effects. The general principles of management are listed in table 2.2.

Simple conservative measures in the management of urinary incontinence
• Exclude urinary tract infection
• Fluid restriction (</=1.5 litres) / timing of intake
• Timed / double voiding
• Provision of a commode
• Barrier cream
• Treat chronic conditions (e.g. cough / constipation)
• Monitor medication (e.g. diuretics)
• Weight reduction (uncertain value)

Table 2.1 Conservative treatment options in the management of urinary incontinence.

Principles of Management of Incontinence
• Establish pathophysiological basis of the disorder
• Try conservative measures first
• Involve the patient in choice of treatment options
• Patient with mixed diagnosis should have the predominant problem treated first
• Provide teaching, counselling and support
• Planned regular review of treatment progress
• Use of both subjective and objective outcome criteria
• Multidisciplinary planning co-ordination and communication
• Regular audit of outcomes and feedback to practitioners

Table 2.2 General principles in the management of incontinence.

Who can benefit from physiotherapy?

It is widely accepted that surgery is the definitive treatment of severe or persistent GSI, but may not be appropriate (table 2.3). Recent studies found that 90% of women with stress incontinence initially decide on a non-surgical treatment and 60% would be willing to try a new non-surgical treatment if offered [1]. Where women have mixed symptoms surgery should only be undertaken with caution and therefore conservative management is pivotal to initial treatment. Age is not a barrier to learning PFEs, but close monitoring is important to ensure correct instructions are carried out and to ensure motivation.

Factors precluding surgery as first line treatment
• Pregnancy or planning pregnancy
• Post partum breast feeding
• Family incomplete
• Medically unfit
• Unwilling to undergo surgery
• Occasional incontinence
• Incontinence not a problem despite severity of urodynamic diagnosis
• Major voiding difficulty

Table 2.3 The main factors precluding surgery as first line treatment.

The rationale is that conservative therapy is relatively inexpensive and readily available, has few complications and does not compromise future surgery (Table 2.4). Individualised exercise programmes optimise the cure rates achievable. The instructor must however be familiar with the chosen technique and flexible in their approach to teaching as no one single technique will suit all. Continence Advisors are invaluable in the overall management [2].

Conservative management of GSI	
Pelvic floor re-education	Pelvic floor exercises Vaginal cones / perineometer
Medication	Drugs acting on the urethra Hormone replacement therapy
Electrical treatment	Faradism * Interferential * Maximal electrical stimulation
Urine collection / drainage	Indwelling catheters (suprapubic and urethral) Clean intermittent self catheterisation (CISC)
Incontinence aids	Pads and pants, commodes
Devices	Tampon / sponge / pessary Adhesive urethral devices Urethral plug devices
Functional incontinence • Commode / prompted or timed voiding • Incontinence aids (pads / pants / catheters) • Adequate laundry facilities • Faecal disimpaction	

Table 2.4 Methods of conservative management used for the treatment of urinary incontinence. * Not routinely used in our department.

Regular review is also required to maintain motivation and encourage the incorporation of these exercises into the daily routine of the woman to ensure the best long-term outcome.

METHODS OF CONSERVATIVE MANAGEMENT

PHYSIOTHERAPY

The urethra is surrounded by striated muscle fibres forming the external sphincter mechanism (Figure 2.1). This sphincter mechanism interdigitates with the musculature of the pelvic floor [3]. It is this relationship between the smooth and striated voluntary muscle in the region of the bladder neck and urethra which forms the rationale for pelvic floor exercises in the treatment of GSI. The aim is to improve the activity of the support musculature of the pelvic floor and thereby aid closure of the sphincter mechanism by a secondary means and thus reduce or prevent urinary leakage.

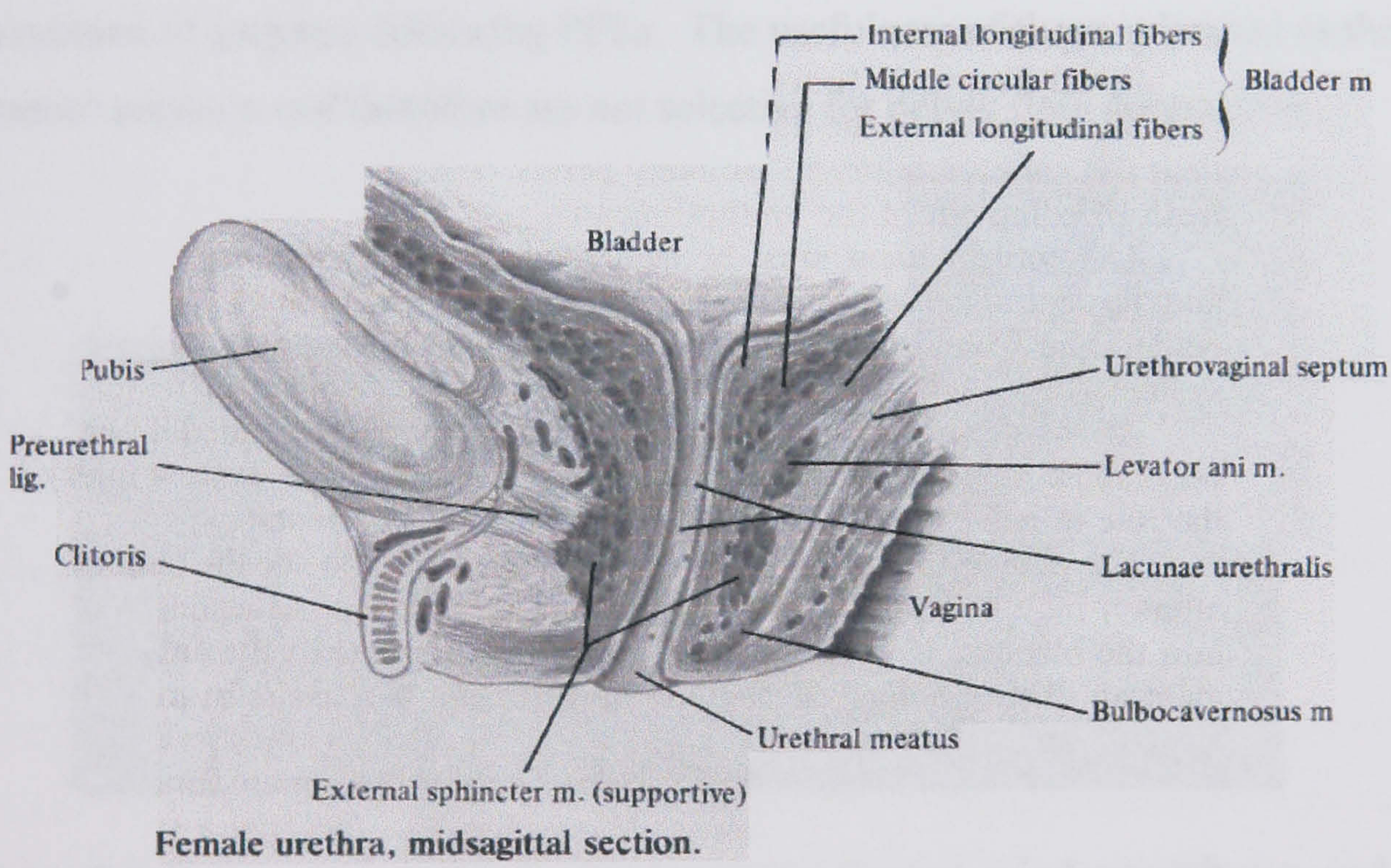


Figure 2.1 The female urethra.

The pelvic floor needs to be in a constant state of muscle activity and be able to respond immediately to any increase in intra-abdominal pressure. Pelvic floor

exercise programmes must cover both of these aspects and should include simple repetitive and stress specific exercises.

PELVIC FLOOR EXERCISES

Pelvic floor exercises were first described by Kegel in 1948 as a method of re-educating the pelvic floor and are still the mainstay of physiotherapy treatment of genuine stress incontinence [4]. Identification and awareness of the pelvic floor musculature and objective assessment of pelvic floor function is important prior to commencing the exercise programme. This can be done by digital examination and contraction of the pelvic floor muscles to squeeze the intravaginal fingers so as to grade the pelvic contraction. An alternative assessment can be obtained using devices such as the perineometer which allow either an analogue or digital read out of the pressure obtained similar to that described by Kegel (1948) (Figure 2.2). The perineometer is a vaginal resistance chamber attached to a meter that registers an increase in pressure when the appropriate muscles contract. Not only is this a helpful method of identifying the pelvic floor musculature but is also a useful objective assessment of progress following PFEs. The usefulness of these is limited as they measure pressure and therefore are not selective for pelvic floor contraction.

Figure 2.2 Perineometer with feedback training through windows software and display.

Pelvic floor contractions can be of two types, fast (lasting 1 sec) and slow (lasting 3-4 sec or more), to exercise both the fast and slow twitch muscle fibres. The length of maximum contraction is also recorded in seconds, as is the number of repetitions performed. A score of 3/4/5 represents a moderate contraction held for four seconds,

which is repeated five times. The incorporation of repetition with endurance exercise is aimed at strengthening both the fast twitch fibres, thought to be important in generating contractions of high pressure and of short duration to counteract transient raised intra-abdominal pressures (for example sneezing), with slow twitch fibres which are important in maintaining resting tone.

No study has been performed to quantify the most appropriate number of contractions required daily. Millard (1987) recommends 10 daily sessions and up to 400 contractions a day, slightly more than that recommended by Kegel (1948) (300 contractions / day) [5]. Women often find this number of contractions excessive, resulting in poor treatment compliance for less motivated subjects. Bo et al (1988) found that one third of women joining their PFE program did not know how to contract their pelvic floor and 70% of women performing PFEs at home were doing them incorrectly [6]. Millard (1987) obtained similar results and suggested that 30% of women were unable to contract their pelvic floor to command and that this may contribute to the failure of PFE's [7]. These patients require remedial tuition to learn the correct exercise.

Results and meta-analysis of PFE's

Although there is much indirect evidence to support the use of these non-surgical treatments for stress incontinence, there is little direct evidence for beneficial effects based on randomised controlled trials. Tapp et al (1989) in a randomised comparison of pelvic floor physiotherapy with the Burch colposuspension in the treatment of GSI found that after six months of treatment 43% of patients treated with PFEs were cured or improved, compared with 96% of the operative group[8]. Cure was defined as an absence of subjective symptoms of incontinence and normal urodynamic investigations. Improvement was either a subjective and/or objective reduction of the degree of incontinence. Interestingly 53% of the PFE group requested surgery at the end of the study.

Kegel's initial work involved 500 women exercising with a perineometer for 20 minutes 3 times a day and 5 contractions ('drawing up and in') every half hour over a six to eight week period. Women were seen weekly to ensure correct muscle contraction and to maintain motivation. In this study 85% of the women were subjectively cured. This was, however, an uncontrolled study with no attempt to

determine the type or degree of incontinence prior to treatment and the results have never been repeated.

Fedorkow (1993) reviewed the existing literature on the non-surgical management of stress incontinence using a strategy which yielded 86 articles [9]. No one method for performing PFEs appeared to be clearly superior. The only adjunct to traditional PFEs which appears to confer benefit over the exercises above is intensive PFEs. These involve regular follow-up, monitoring and encouragement in the continued performance of traditional PFEs

COMPLIMENTARY THERAPIES

Some women performing pelvic floor exercises show improvement in leakage episodes soon after starting such a program or long before any muscle hypertrophy can have taken place. Indeed, Miller et al (1996) found that a precisely timed volitional levator ani muscle contraction, learned in one week, was a simple and efficient technique to reduce urine leakage by over 60% during a cough [10].

POSTURAL CHANGES

In a study by Norton and Baker (1994) most women with GSI could reduce or eliminate urine loss using postural changes with coughing [11]. A combination of crossing the legs and bending forward was effective, but bending forward alone was not sufficient while crossing one's legs was the most effective position and produced continence in nearly 73% of subjects. The mean reduction in fluid loss was 14.7g (95% CI = 21.2g to 8.2g) using the best posture compared with the standing position. However, postural changes are not useful in reducing urine loss associated with walking, running, jumping or other activities involving movement of the lower limbs. The mechanism of action is unknown but it is postulated that crossing the legs may compress the urethra or alter the tone of the pelvic floor and aid closure of the sphincter mechanism.

BIOFEEDBACK

Women often have difficulty isolating the pelvic muscle groups and to overcome this, adjunctive "biofeedback" therapies have been developed to assist the correct performance of these exercises [12]. These include the use of a perineometer, vaginal cones and electrical stimulation.

The perineometer can be used to aid pelvic floor exercises by enabling the woman to gauge the strength of the contraction which she generates (Figure 2.2). The use of a perineometer is easy to teach and requires less follow-up supervision. They are generally acceptable to all women and are useful in improving compliance to traditional pelvic floor exercises which still form an essential part of treatment.

VAGINAL CONES

Plevnik (1985) showed that women could learn to contract the muscles of the pelvic floor by retaining cones of increasing weight in the vagina [13]. The feeling of losing the cone helps to identify and assess the muscles of the pelvic floor. Pelvic floor contraction is essential to keep the weights in the vagina as contracting the abdominal or gluteal muscles will not aid retention of the cones. A set of vaginal cones consists of weights ranging from 20 to 100g with a nylon thread to facilitate removal (Figure 2.3). A cone is inserted into the vagina, base uppermost, and the heaviest weight retained without voluntary holding is called the passive weight, reflecting resting pelvic floor tone. The heaviest weight retained with voluntary pelvic floor contraction is the active weight.

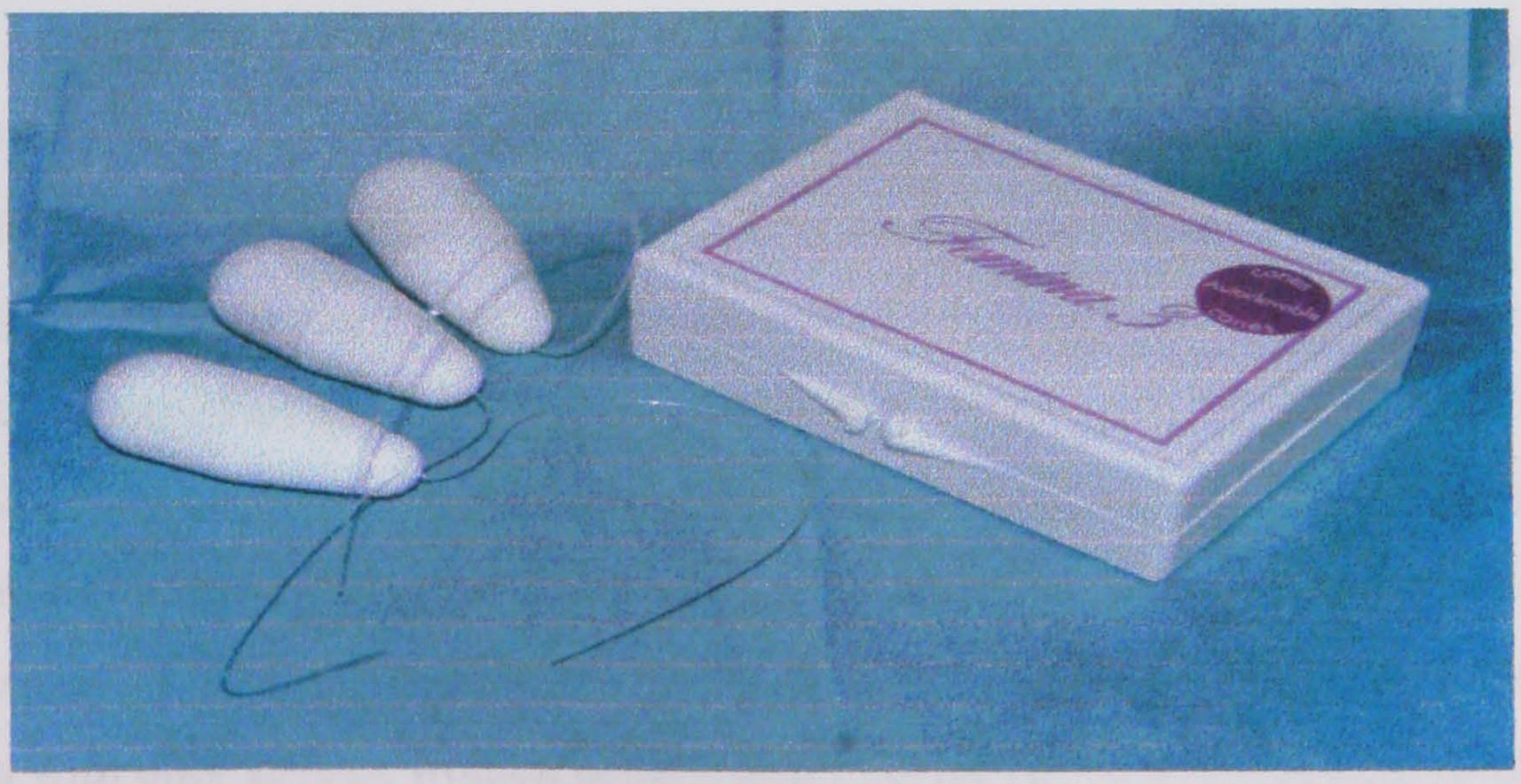


Figure 2.3 Vaginal cones.

Starting with the passive weight the patient is asked to insert and retain the cone in the vagina for 15 minutes twice a day. Once successful on two consecutive occasions she progresses to the next weight. By gradually increasing the cone weight, the strength of the pelvic floor contractions will increase and the woman can monitor her progress.

In the short term, upwards of 70% of patients are cured or improved and 90% find it an acceptable method of treatment. However, these results are not sustained in the long term [14 15].

ELECTRICAL STIMULATION

FARADISM AND INTERFERENTIAL THERAPY

Electrical stimulation can take the form of Faradism or Interferential therapy. Faradism involves the passage of a low frequency current of bearable but sufficient strength to stimulate the levator ani muscles of the pelvic floor. Two electrodes are used, one placed over the sacrum and a second placed on the perineum or in the vagina.

Alternatively interferential produces a low frequency stimulating current by the passage of two cross firing medium frequency currents applied from different directions. The point of maximal stimulation is the peak intersection of these currents and this produces a contraction of the muscle. Four electrodes are usually used, two attached to the abdomen and two to the adductor muscles of the thigh. This technique is thought to allow a greater degree of stimulation of the designated muscle group. The aim of treatment is to re-educate awareness of muscle contractility and increase muscle tone.

Sand et al (1995) conducted the first prospective randomised, double blind, placebo controlled trial of transvaginal electrical stimulation with no adjunct strength training to treat GSI [16]. There was also a 32% cure/improvement rate on pad testing in the control group, demonstrating a significant benefit from the placebo devices. They compared the use of an active pelvic floor stimulator with a sham device over 15 weeks. Significant improvement in pelvic floor muscle strength and GSI were found in the women using active devices but not in controls. Pad testing showed that stress incontinence was improved by at least 50% in 62% of patients using an active device compared with only 19% of women using a sham device ($p = 0.01$). Voiding diaries also showed at least 50% improvement in 48% of active-device patients compared

with 13% of women using a sham device ($p = 0.02$). Probably one of the most limiting factors in the use of electrical stimulation is the high incidence of side effects. No irreversible adverse effects were noted in either group but 50% experienced side effects with the active stimulator including vaginal irritation, pain, vaginal infections and UTIs.

MAXIMAL AND LONG TERM STIMULATION

The underlying principle is the stimulation of a sustained contraction of the urethral and periurethral striated muscles by vaginal or rectal electrodes to increase urethral pressure. Stimulators consist of a battery operated portable pulse generator connected to a vaginal or anal plug electrode (Figure 2.4).

Figure 2.4 Pelvic floor electrical stimulators with vaginal and anal probes.

In conditions with incompetent urethral closure mechanism, long term stimulation on a daily basis with a programmable stimulator appears to give the best efficacy.

Despite its use for over two decades maximal electrical stimulation has still not achieved widespread approval. Improvement rates with electrical stimulation vary widely from study to study and with the same device. Improvement rates varying from 35% to 70% and cure rates ranging from 0% to 50% have been reported [17].

Practical points in the conservative management of GSI
• Pelvic floor exercises are useful in the treatment of many forms of urinary incontinence
• Motivation is the most important factor
• Patients require detailed assessment to optimise results
• Tailored exercise programmes give the best outcome
• Treatment takes 3-6 months to demonstrate improvement
• Exercises need to be continued long term to maintain any benefit

Table 2.5 Practical points in the conservative management of GSI.

In a proportion of women, incontinence is intractable and the aim of management is to minimise the severity of the problem and render her socially continent. This may be achieved with the use of absorbent pads, pants and indwelling catheters. Toileting aids which may enable continence, such as hand-held urinals, commodes and toilet adaptations are used. Table 2.5 illustrates some practical points in the conservative management of GSI.

SURGICAL MANAGEMENTOF GSI

Continence surgery is warranted when conservative measures fail or when definitive treatment is indicated. Surgery carries a risk of morbidity and mortality which should not be overlooked. It is also used to correct a urethral diverticulum, stricture, fistula or congenital abnormality and severe refractory urethral incompetence.

Black and Downs (1996) have made some disturbing observations in their relatively recent systematic review of eleven randomised controlled trials, 20 non-randomised trials/prospective cohort studies and 45 retrospective cohort studies [18]. The objective of this review was to determine the methodological quality of studies evaluating the effectiveness of surgery for GSI and the frequency of complications associated with each procedure. They found that the methodological quality of the prospective studies reporting effectiveness of surgery was poor so it would be difficult and speculative to draw conclusions about efficacy and value of the different procedures. They found that there was inadequate case definitions, variations in how surgical procedures are undertaken, low external validity, ill defined outcomes with no evidence of the reliability and validity of measurements, lack of patient-perceived

outcomes regarding quality of life, insufficient statistical power and inadequate handling of confounding variables. Valid and reliable data on the frequency of complications following surgery were lacking, so the safety of the procedures was unclear.

There is no prevailing agreement as to the surgical procedure of choice for women with GSI. Surgical procedures to remedy stress incontinence generally aim to elevate and/or support the urethro-vesical junction, but there is disagreement about the precise mechanism by which continence is achieved (table 2.6) [19]. The clinical guidelines panel of the American Urological Association recently analysed 457 articles on outcome data for potential benefits and risks of surgical approaches to treating GSI in women [20]. The found that the currently available surgical literature regarding GSI demonstrated that after 48 months, retropubic suspensions and sub-urethral slings offer greater chance of success than do transvaginal suspensions or anterior repairs.

Surgical approach for the Treatment of genuine stress incontinence

OPERATION	INDICATION
1.Anterior colporrhaphy (combined with Kelly or Pacey buttressing sutures)	Significant uterovaginal prolapse, but seldom the procedure of choice for Primary GSI.
2.Marshall-Marchetti-Krantz procedure	Primary or secondary GSI
3.Colposuspension	Primary or secondary GSI
4.Long needle bladder neck suspensions, (Pereyra or Stamey)	GSI in the surgically difficult pelvis
5.Sling procedures*	Severe recurrent GSI
6.Periurethral injectables	Surgically difficult pelvis
7.Complex surgical procedures** (e.g. artificial sphincter, neourethra)	Intractable recurrent urethral sphincter incompetence

Table 2.6 Surgical approach for the treatment of genuine stress incontinence. ** Not available in our unit, * Not routinely performed

The success and adverse events associated with these procedures have been reviewed by Jarvis (1994) (Table 2.7) [21]. He showed that despite operator preferences, the current literature showed that no single procedure should be advocated for all women with genuine stress incontinence. Evidence would suggest that suprapubic procedures such as the Colposuspension have excellent subjective and objective cure rates, although are more often associated with side effects and surgical complications.

Success rates of continence surgery		
Operation	**First procedure (% continent)**	**Recurrent incontinence (% continent)**
Bladder Buttress	67.8	N/A
Marshall-Marchetti-Krantz	89.5	N/A
Colposuspension	89.8	82.5
Endoscopic bladder neck Suspension	86.7	86.4
Sling procedures	93.9	86.1
Injectables	45.5	57.8

Table 2.7 Success rates of continence surgery. [Jarvis (1994)]

ANTERIOR COLPORRHAPHY

In comparison with abdominal surgery, the vaginal approach is simpler, resulting in less operative morbidity fewer complications and requiring a shorter in-patient hospital stay. Anterior colporrhaphy has been used to treat primary GSI in the presence of a cystourethrocele but whilst this is the best operation for the treatment of anterior vaginal wall prolapse, it is not the best treatment of GSI [21]. The technique involves an anterior longitudinal vaginal wall incision, mobilisation of the bladder neck and the insertion of Kelly or Pacey sutures to elevate the bladder neck, prior to approximation of the pubovesical fascia and closure of the vaginal wall [22 23] (Fig 2.5).

Figure 2.5 Stages in an Anterior Repair.

COLPOSUSPENSION

The colposuspension was described by Burch in 1961 and has since been modified by a number of different authors [24]. Indeed the Burch colposuspension is one of the most effective surgical procedures for the cure of GSI in women. No other operation has been demonstrated to work more successfully either in randomised or non-randomised comparisons [25 26 27 28]. Although it is normally performed through a low transverse suprapubic incision, recent attempts have been made to carry out laparoscopic colposuspension. The success rates are very good, but randomised trials with open surgery are awaited [29].

Retropubic dissection is required to mobilise the bladder neck medially off the underlying fascia, prior to the insertion of two to four long term absorbable or non-absorbable sutures from the paravaginal fascia to the ipsilateral ileopectineal ligament (Figure 2.6).

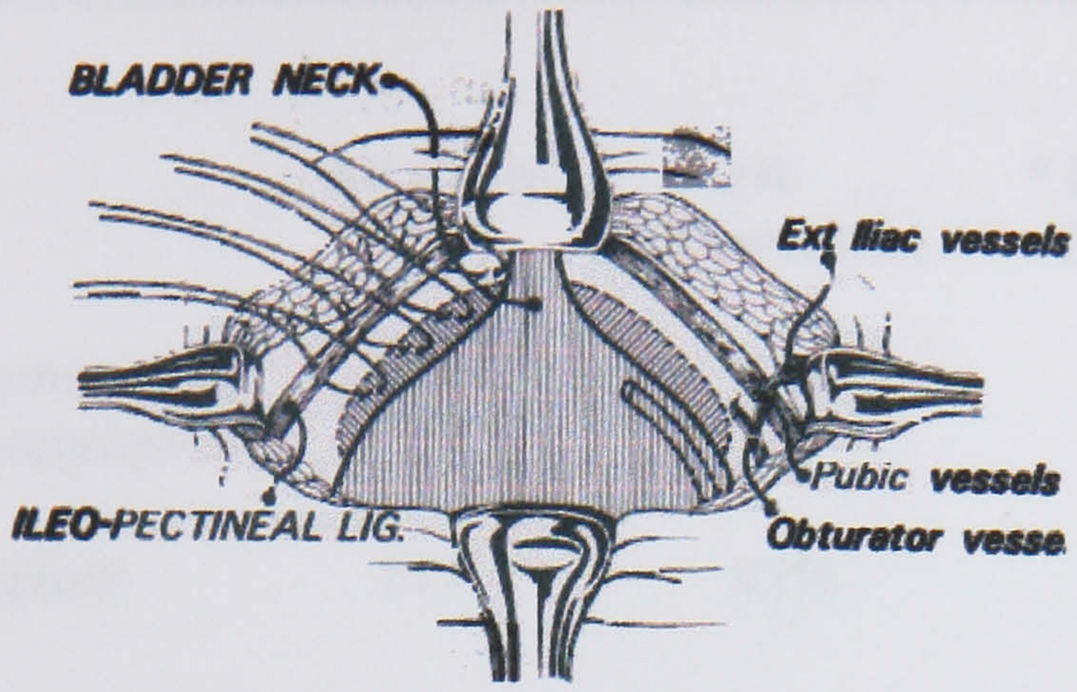


Figure 2.6 Suture placement at colposuspension.

The complications of this procedure include operative blood loss, urinary tract damage and infection and the later problems of voiding difficulties, detrusor instability and enterocele or rectocele formation.

It is important to be aware of the success rates of surgery locally. In a subjective and objective analysis of the results of 100 colposuspensions performed at King's College Hospital (1996-1997), a subjective cure rate of over 90% and objective urodynamic cure rate of over 80% was found 9 months after surgery (Cardozo unpublished data), (Table 2.8). Cardozo et al (1999) also reported the outcome of colposuspension in 52 women who had previously undergone bladder neck surgery at KCH (Table 2.8) [30].

Analysis of 100 primary colposuspensions performed at King's College Hospital and 52 performed as a repeat operation

A. Cure rate

Assessment	**All Cases**	**First Operation**	*** Repeat Operation**
Objective (Cystometry and Videocystourethrography)	82%	91%	78%
Subjective (Symptom Analysis)	81%	93%	80%

B. Improvement rate

Assessment	**All Cases**	**First Operation**
Objective (Cystometry and Videocystourethrography	91%	93%
Subjective (Symptom Analysis)	90%	96%

Table 2.8 Analysis of 100 colposuspensions performed at King's College Hospital as a primary procedure and 52 women having repeat surgery. { (1991-1992) (Cardozo, unpublished data)} * Cardozo et al 1999.

MARSHALL-MARCHETTI-KRANTZ

The MMK procedure (Marshall, Marchetti & Krantz, 1949) is the predecessor of the colposuspension. It involves the insertion of sutures between the paravaginal fascia on either side of the bladder neck and the periosteum of the pubis (Figure 2.7).

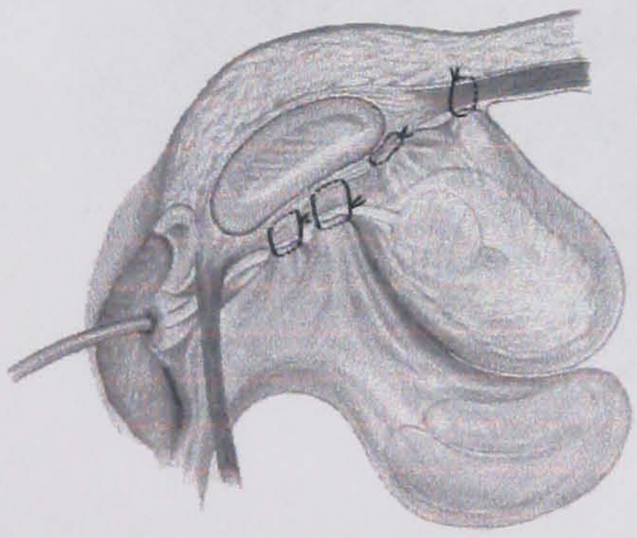


Figure 2.7 Suture placement during a Marshall, Marchetti & Krantz procedure.

Although this is a very successful operation for the treatment of GSI, it does not treat anterior vaginal wall prolapse and osteitis pubis may be a post-operative problem occurring in about 5% of cases [31].

ENDOSCOPICALLY GUIDED BLADDER NECK SUSPENSION

Many different endoscopically guided procedures have been described and utilise two nylon sutures passed blindly from the paravaginal fascia to the rectus sheath or vice versa.

Figure 2.8 Suture placement during an endoscopically guided procedure.

They are easier to perform than procedures in the surgically difficult pelvis where recurrent surgery has made the usual anatomical landmarks less discernible. The cure rates are less than that following colposuspension or MMK.

SLINGS

These procedures are advocated for the treatment of recurrent GSI especially where there is limited mobility of the anterior vaginal wall and bladder neck and a deficient urethral sphincter

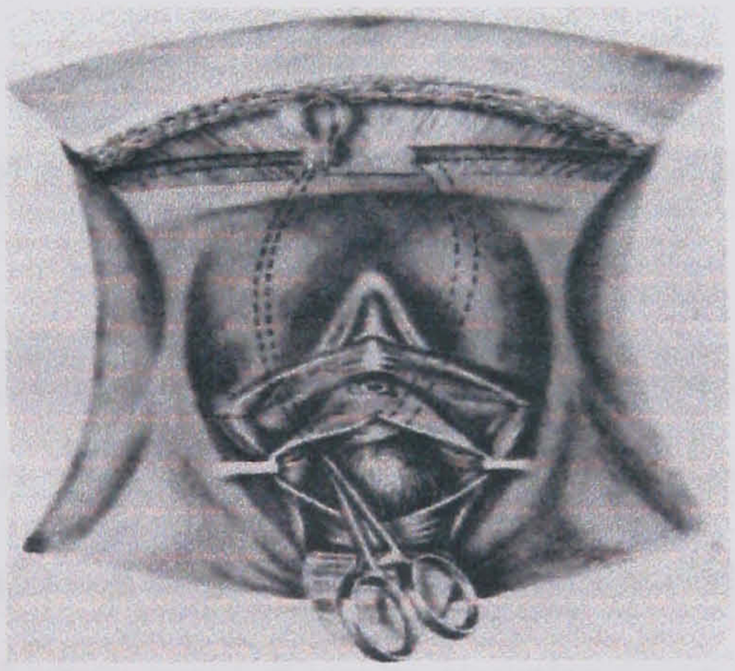


Figure 2.9 Sling.

The sling can be fashioned from organic material, strips of the patients own rectus sheath or fascia lata or inorganic material such as Mersilene or Goretex. Cure rates appear to be high, however, complications including voiding difficulties are common

following these operations sometimes requiring clean intermittent self-catheterisation indefinitely

PERIURETHRAL INJECTIONS

Periurethral injections of bulking material have been used extensively in treating women with GSI [32]. Injections of bulk-enhancing agents in the periurethral tissues with its simplicity, low morbidity and repeatability have been suggested as an alternative to classical surgical approaches particularly for patients who are poor candidates for open surgery [33]. The bulking of the proximal urethra is thought to improve the urethral seal by reapposition of the urethral mucosa. Published reports have shown a 60-90% early cure and improvement rates [34]. These figures seem to decrease with time and repeated injections may be necessary to produce a long-term satisfactory result.

COMPLEX PROCEDURES (RESTORATION OF OUTLET RESISTANCE)

When repeated attempts have failed to restore outlet resistance in severe GSI insertion of an artificial sphincter or the construction of a neo-urethra is indicated. These complex surgical procedures have an accordingly high morbidity and are usually only performed in specialist centres.

PHARMACOLOGICAL TREATMENT

Pharmacotherapy using drugs, which increase outlet resistance, has been advocated in the treatment of stress incontinence. The nerves of the bladder and urethra arise from both the somatic and autonomic nervous systems. Somatic innervation is mediated through the pudendal nerve. Autonomic nerves supplied via the pelvic plexus provide both sympathetic and para-sympathetic innervation. Alpha-adrenergic receptors are most prominent at the urethrovesical junction and along the length of the urethra. Stimulation results in smooth muscle contraction and an increase in the maximum urethral closure pressure. It is this relationship, along with finding of oestrogen

receptors in the bladder, urethra and surrounding tissues, which are the foundations for the various pharmacotherapies.

PHENYLPROPANOLAMINE

Phenylpropanolamine hydrochloride (PPA), a pure alpha-adrenergic stimulator has been used in the treatment of stress incontinence. Descriptive studies have reported beneficial effects on stress incontinence and in comparison studies consistently positive treatment effects have been noted. Overall however it has been shown that not only are the results modest in the treatment of stress incontinence but may have considerable side effects.[35]

OESTROGEN THERAPY FOR STRESS INCONTINENCE

For continence to exist a positive urethral closure pressure is produced by the four functional layers of the urethra; namely the epithelium, connective tissue, vascular tissue and muscle. All these layers are affected by oestrogen status [36 37]. These accounts as well as the epidemological data indicating that urinary incontinence is particularly prevalent among older post menopausal women have led to the hypothesis that the lack of oestrogen is a factor in the development of urethral sphincter incompetence and bladder dysfunction. An extension of this is that oestrogen replacement may be of value in the treatment of genuine stress incontinence [38]. Oestrogens may aid continence by increasing urethral resistance, raising the sensory threshold of the bladder, increasing alpha receptor sensitivity in the urethral smooth muscle, or possibly by a combination of all three. In addition oestrogen therapy has been shown to increase the number of intermediate and superficial cells in the vagina of postmenopausal women and similar changes have been demonstrated in the urethra and bladder [39 40]. Urodynamic testing has also shown that variations in oestrogenic states influence urethral closure pressure urethral pressure transmission and the vascular pulsations around the continence mechanism [41].

In a randomised, placebo-controlled, double blind trial, Fantl et al (1996) assessed the efficacy of cyclical conjugated oestrogens (0.625mg) and medroxyprogesterone (10mg) cyclically for 3 months in treating urinary incontinence [42]. Eighty-three

hypoestrogenic women with evidence of genuine stress incontinence and/or detrusor instability were included. They concluded that therapy did not affect either clinical or quality of life variables of incontinent, hypoestrogenic women.

However, Sartori et al (1995) managed thirty postmenopausal women with genuine stress incontinence but without detrusor instability [43]. They used conjugated estrogens and progesterone for 3 months but without a control group. Forty-six percent of women were judged to be cured and 43% markedly improved. Maximum urethral closure pressure, maximum cystometric capacity and mean flow were significantly increased. Residual urine and diurnal and nocturnal voluntary micturition were markedly decreased ($p< 0.05$).

Fantl et al (1994) applied a meta-analysis to available data to evaluate the efficacy of oestrogen therapy in the management of postmenopausal women with urinary incontinence [44]. They found an overall significant effect of oestrogen therapy on subjective improvement for all subjects ($p <0 .01$) and for subjects with genuine stress incontinence alone ($p < 0.05$). The results showed no significant effect on quantity of urine loss but a significant effect ($p < 0.05$) on maximum urethral closure pressure. It would appear from this analysis that oestrogen subjectively improves urinary incontinence in postmenopausal women. However, the studies included nonhomogeneous groups, and the diagnostic criteria, therapeutic interventions, and outcome assessments varied considerably.

Sultana and Walters (1994) reviewed the efficacy of oestrogen therapy for urinary incontinence by examining published trials and to review the epidemiological and physiologic evidence for its action [45]. Eight controlled and 14 uncontrolled prospective trials were identified. All types of oestrogen treatment and outcome measurements were included. They concluded that the published trials did not support oestrogen replacement as efficacious therapy for stress urinary incontinence. It may however, be useful for incontinence associated with urgency and frequency.

CONCLUSION

The corner stone of effective management is making an accurate diagnosis of the type and cause of incontinence. The overall effect is seldom the result of a single underlying factor, so a thorough evaluation is vital. Management depends on the health and expectations of the sufferer, her misery and disruption to her quality of life

as well as the clinical findings. Urinary symptoms are remarkably unreliable and there is often a discrepancy between urinary complaints and the results of diagnostic tests. Hence, urodynamic investigations may be necessary. Other pelvic pathology may be present and must be actively sought and treated as incomplete therapy or therapy for these pelvic disorders at a future date may be detrimental to previously successful management of incontinence.

Pelvic floor exercises are a non-invasive and safe method of treating stress incontinence. The treatment takes 3-6 months to be effective and must be maintained long term. Patients who tend to have a more successful outcome following PFEs are younger, better motivated, have a shorter duration and lesser degree of GSI and have not undergone previous pelvic surgery. It is important to recognise that improvement in symptoms rather than an absence of incontinence episodes is the more common outcome reported in non-surgical studies and this ought to be anticipated.

Physiotherapeutic adjuncts require additional equipment and costs and do not appear to be clearly better than conventional PFE's. Support is essential for women to cope with their problems and periodic review to assess a change in the clinical picture or the possibility of a new therapeutic option is essential. Community services are now more readily available than before and a great deal of help can be given which enables an older person to remain at home. It is hoped that this is one area in which devices may be of benefit to this age group.

The need for secondary specialist referral is quite clear in most cases. Women should be referred if initial conservative therapy fails after a reasonable trial of at least 6 months. Referral may also be indicated in women with concurrent gynaecological problems such as uterovaginal prolapse or menstrual dysfunction which require treatment or in cases of recurrent incontinence following surgery. Urodynamic testing should be used to confirm the cause of incontinence before selecting a surgical procedure.

References

[11] American Foundation for Urologic Disease (AFUD). Report of the Bladder Healt Council, Baltimore, April 1995

[2] Smith N. Continence advisory services in England. Health Trends 1988;20:22-4

[3] Oelrich T. The striated urogenital sphincter muscle in the female. A Nat Rec. 1983;205:223-34

[4] Kegel AH. Progressive resistance exercise in the functional restoration of the perineal muscles. Am J Obstet Gynecol 1948;56:238-248

[5] Millard R.J. Bladder control, a simple self-help guide. p21 . Sydney. Mclennon and Petty Ltd, 1987.

[6] Bo K,. Larson S., Oseid S., Kuarstein B. Knowledge about the ability to correct pelvic floor muscle exercises in women with urinary stress incontinence. Neurourol and Urodynam 1988; 7, 261.

[7] Millard RJ. Overcrowding Urinary Incontinence. Wellingborough. Thorsons 1987

[8] Tapp AJS, Hills B, Cardozo LD. Randomised study comparing pelvic physiotherapy with Burch colposuspension. Neurourol Urodynam. 1989;8:356-357

[9] Fedorkow D. Non surgical management of stress urinary incontinence. Journal SOGO 1993; 695-705.

[10] Miller J, Ashton-Miller J, DeLancey J. The Knack: use of precisely-timed pelvic muscle contractions can reduce leakage in SUI. Neurourol Urodynam 1996, 15(4):392-393.

[11] Norton P, Baker J. Postural changes can reduce leakage in women with stress urinary incontinence. Obstet Gynecol 1994;84:770-4.

[12] Burgio KL, Robinson JC, Engel BT. The role of biofeedback in Kegel exercise training for stress urinary incontinence. Am J Obstet Gynaecol 1986 1986;154:58-63

[13] Plevnik S., Holmes D.M. Urethral electrical conductance (UEC)- a new parameter for evaluation of urethral and bladder function: methodology of the assessment of its clinical potential. In: Proceedings of the Fifteenth international Continence Society Meeting, London.1985; 90-91.

[14] Bridges N, Denning J, Ollah K, Farrar D 1988. A prospective trial comparing Interferential therapy and treatment using cones in patients with symptoms of stress incontinence. Neurourol. Urodynam. 1988: 7: 267-8

[15] Kato K, Kondo A, Hasegawa S. Pelvic floor muscle training as treatment of stress incontinence. The effectiveness of vaginal cones. J. Urol. 1992;83: 498-504

[16] Sand P, Richardson D, Staskin D et al. Pelvic floor electrical stimulation in the treatment of genuine stress incontinence: a multicentre, placebo-controlled trial. Am J Obstet Gynecol 1995;173(1):72-9

[17] Jonasson A, Larsson B, Pschera H, Nylund L. Short-term maximal electrical stimulation – a conservative treatment of urinary incontinence. Gynecol Obstet Invest 1990;30:120-3

[18] Black N, Downs S. The effectiveness of surgery for stress incontinence in women: a systematic review. Br J Urol 1996;78:497-510

[19] Stanton S. Stress incontinence. Why and how operations work. Urol Clin North Am 1985;12:279-84

[20] Leach G, Dmochowski R, Appell R, Luber K et al. Female stress urinary incontinence clinical guidelines panel summary report on surgical treatment of female stress urinary incontinence. Int Urogynecol J 1997;8(1):S70

[21] Jarvis G. Surgery for genuine stress incontinence. Br J Obstet Gynecol, 1994. 101(5): 371-4.

[22] Kelly H.A., Dumm W.M. Urinary incontinence in women, without manifest injury to the bladder. Surg Gynaecol Obstet 1914; 1 8, 444-450.

[23] Pacey K. Pathology and repair of genital prolapse. J Obstet Gynaecol Br Empire 1949; 56, 1-1 5.

[24] Burch J. Urethro-vaginal fixation to Coopers ligament for correction of stress incontinence, cystocele and prolapse. Am J Obstet Gynaecol 1961; 1:20, 61-3.

[25] Bergman A, Ballard CA, Koonings PP. Comparison of three different surgical procedures for genuine stress incontinence: prospective randomised study. Am J Obstet Gynecol 1989;160:1102-6

[26] Colombo M, Scalambrino, Maggioni A, Milani R. Burch colposuspension versus modified Marshall-Marchetti-Krantz urethropexy for primary genuine stress urinary incontinence: a prospective randomised clinical trial. Am J Obstet Gynecol 1994;171:1573-9.

[27] Mundy AR. A trial comparing the Stamey bladder neck suspension procedure with colposuspension for the treatment of stress incontinence. Br J Urol 1983;55:687-91.

[28] Stanton SL, Cardozo LD. A comparison of vaginal and suprapubic surgery in the corrections of incontinence due to urethral sphincter incompetence. Br J Urol 1979;51:497-9.

[29] Su T, Wang K, Hsu C, Wei H, Hong B. Laparoscopic versus open colposuspension for genuine stress incontinence. Acta Obstet Gynecol Scand 1997;76:576-82

[30] Cardozo L, Hextall A, Bailey J, Boos K. Colposuspension after previously failed incontinence surgery: a prospective observational study. Br J Obstet Gynaecol 1999, 106: 340-344.

[31] Stanton S. L. Suprapubic approaches for stress incontinence in women JAGS 1990; 38, 348-351.

[32] Benshushan A, Brzezinski A, Shoshani O, Rojansky N. Periurethral injection for the treatment of urinary incontinence. Obstet Gynaecol Surv, 1998. 53(6): 383-8.

[33] Swami S, Batista J, Abrams P. Collagen for female Genuine Stress Incontinence after a minimum 2 year follow-up

[34] Chaliha C, Williams G. Periurethral injection for the treatment of urinary incontinence. Br J Urol, 1995. 76(2): 151-5.

[35] Mostwin J. Effects of pharmaceuticals on bladder functions. Curr Opin Obstet Gynecol 1990;2:580-4

[36] Iosif C, Batraa S, EK A, Asted EB. Estrogen receptors in the human female lower urinary tract. Am J Obstet Gynecol 1981;141:817-20

[37] Brincat M, Moniz C, Studd J, Darby A, Magos A, Cooper D. Sex hormones and skin collagen content in postmenopausal women. Br Med J 1983;287:1337-8

[38] Fantle A, Cardozo L, Ekberg J, McClish D. Estrogen therapy in the management of urinary incontinence in postmenopausal women: A meta-analysis. First report of the Hormones and Urogenital Therapy committee. Obstet Gynecol 1994;83:12-8

[39] Smith PJB. The effect of oestrogens on bladder function in the female in the management of the menopause and post-menopausal years. (Ed) Campbell S (MTP), 1976; 291-298.

[40] Samsioe G, Jansson I, Mellstrom D, Svandborg A. Occurrence, nature and treatment of urinary incontinence in a 70 year old female population. Maturitas 1985; 7: 335-342.

[41] Versi E, Cardozo LD, Brincat M, Studd J. Lower urinary tract symptoms urodynamic findings and skin collagen in normal postmenopausal women. Maturitas 1984;6:204-5

[42] Fantl JA, Bump RC, Robinson D, McClish DK, Wyman JF. Efficacy of estrogen supplementation in the treatment of urinary incontinence. The continence program for women research group. Obstet Gynecol 1996; 88(5): 745-9.

[43] Sartori MG; Baracat EC; Girao MJ; Goncalves WJ; Sartori JP; de-Lima GR . Menopausal genuine stress urinary incontinence treated with conjugated estrogens plus progestogens. Int-J-Gynaecol-Obstet. 1995; 49(2): 165-9

[44] Fantl JA, Cardozo LD, McClish DK et al. Oestrogen therapy in the management of urinary incontinence in post-menopausal women: a meta-analysis. First report of the hormones and urogenital therapy committee. Obstet Gynecol 1994; 83: 12-18.

[45] Sultana CJ, Walters MD. Estrogen and urinary incontinence in women. Maturitas 1994; 20(2-3): 129-38

CHAPTER THREE

QUALITY OF LIFE AND IMPACT OF URINARY INCONTINENCE

EFFECT ON HEALTH

Loss of urinary control is a distressing and disabling condition causing significant morbidity within society. It affects the social, psychological, occupational, domestic, physical and sexual lives of 15-30% of women of all ages [1]. Sufferers give up many aspects of their usual lifestyle with obvious detriment to their social interactions, interpersonal and sexual relationships, careers and psychological wellbeing. Activities such as household chores, physical recreation and hobbies are often particularly affected and a new way of life organised around the location of toilets and the avoidance of potentially embarrassing situations develop.

Incontinence also has a social stigma in that women may severely restrict their activities due to fear of urine loss and concerns about odour in public [2]. Many factors affect the perception of incontinence as a significant health problem including, culture, diagnosis, race, social class, marital status, sexual problems, duration of symptoms and the severity of the urinary leakage.

Norton et al (1988) in their study of women referred for urodynamic assessment found significant delay from the time the urinary symptoms first become troublesome until a general practitioner's advice was sought [3]. Two fifths of women consulted a doctor within one year of symptoms becoming troublesome. A third delayed for 1 – 5 years and a quarter waited more than five years. The most frequently reported restrictions on their daily life were avoidance of fluids and the need to wear pads. They were less able to carry or lift as part of their daily activities, avoided public transport or going far from home. More than half of the women felt their urinary problems affected their work. They very often felt odd and different and less attractive because of their symptoms and would avoid other people. The study also highlighted the fact that up to 50% of adult women with urinary incontinence avoid sexual activity through fear of leakage.

An equally distressing finding is that many women who do tell their doctor about their urinary symptoms are told either to live with them, or briefly instructed to do pelvic floor exercises without training or explanation. Often patients do not benefit from this advice reinforcing the belief that little can be done to help their incontinence and spreading this pessimistic outlook to their friends and relatives.

IMPACT ON MENTAL HEALTH

Serious psychiatric morbidity has been reported in 25% of women attending a urodynamic assessment clinic [4]. The psychological effects of urinary incontinence can be more devastating than the social and health consequences. Many women, particularly older patients suffer intense embarrassment, loss of self-esteem, depression, anxiety and feelings of helplessness, all of which contribute to reluctance to stray far from toilet facilities and to withdraw from social contacts [5]. Psychosocial problems and urinary incontinence thus appear to be related although it is unclear whether psychological distress is a result or a cause of lower urinary tract dysfunction. Research would suggest that, for the majority of women, the former is true as both the objective and subjective severity of urinary incontinence correlate significantly with the degree of psychological disturbance [6].

SEXUAL PROBLEMS AND URINARY INCONTINENCE

Sexual dysfunction is a common cause of morbidity amongst incontinent women and as such demands particular mention. There are many reasons why urinary incontinence and sexual dysfunction are associated apart from the close proximity of the urinary and genital tracts. Many incontinent women are embarrassed or ashamed of their condition and studies have shown that incontinence can result in deterioration in women's interpersonal relationships [7]. Lack of libido and diminished self esteem due to a fear of leakage are major factors, however urinary leakage during penetration or at orgasm, as well as dyspareunia secondary to urine dermatitis or incontinence surgery, play a major roll.

Over fifty per cent of sexually active incontinent women suffer sexual dysfunction as a result of their urinary symptoms and one in four are incontinent during sexual intercourse[8]. Long-standing urinary symptoms and sexual difficulty are however, a source of appreciable morbidity and can, once established become incorporated into an individual's lifestyle and personality. This may have major implications for the management of incontinent women, as the successful treatment of lower urinary tract symptoms may not necessarily improve their sexual dysfunction.

ECONOMIC ISSUES AND URINARY INCONTINENCE

Studies of the economic impact of urinary incontinence are scarce, primarily because of the varying results of prevalence studies, the absence of reliable risk factor analysis and cost data and wide diversification of treatment strategies. Most of the available data has been collected in the United States of America and has focused on the cost of caring for incontinent people in nursing homes. Health care costs of urinary incontinence in the USA and Sweden account for about 2% of the national health care budgets and Hu et al (1994) estimated cost of managing incontinence in the USA grew from $8.1 billion to $10.3 billion [9 10]. These studies highlighted the direct and indirect costs of urinary incontinence. Direct costs include those required to diagnose, treat, care for and rehabilitate incontinent patients. Indirect costs include lost productivity of patients and unpaid carers and other expenses due to ill health. Based on multiple assumptions regarding incontinence prevalence rates and cost information, the entire economic cost in 1984 of urinary incontinence was $8.1 billion; $6.6 billion direct costs and $1.5 billion indirect costs. Costs incurred by nursing homes, which were all direct costs, totalled $1.8 billion which represented about 10% of nursing home expenditure.

The exact financial cost of incontinence in the UK is unknown [11]. The health care costs when transposed to the UK population are thought to be similar and equates to £1.4 billion per annum for our population of 56 million. It has been estimated in 1991 that the NHS spends £56 million per year on continence products, of which £36 million is spent on absorbents, mostly disposables and £20 million on devices [12].

The direct cost of pads and appliances used in UK hospitals and long-term care facilities in 1986 was over £50 million, with a further £18 million in prescription items in England and Wales [13]. These costs are simply for the containment of urinary incontinence.

Financial constraints within an already over-utilised and under-funded health service have introduced the need for effective cost utility analysis, resource allocation and "needs assessment". The economic burden of continence care is considerable but difficult to accurately quantify. Whether the investigation and treatment of urinary incontinence actually decreases the economic burden of urinary incontinence is unproven but likely to be the case. Ouslander and Kane (1983) showed that active evaluation and treatment of nursing home residents resulted in considerable cost

savings [14]. Irrespective of direct financial incentives, the effective treatment of urinary incontinence considerably improves the quality of life of sufferers; the cost of which is difficult to quantify.

AGE AND URINARY INCONTINENCE

Although urinary incontinence is not specifically a condition of the elderly, several small scale studies have reported the commonly held belief that incontinence is a normal part of ageing. A study by Gjorp (1987) found that 72% of a sample of 79 elderly women with genitourinary symptoms felt them to be normal for elderly people [15].

Norton et al (1988) have shown that elderly women tend to present later for the assessment and treatment of urinary incontinence [16]. This may be due to a greater tolerance of urinary symptoms or the reluctance of doctors to refer elderly women for urodynamic assessment. Mitteness (1987) and Simons (1985) have shown that a substantial number of incontinent women are told that there is little that can be done to help their incontinence and that it is a normal part of ageing [17] [18]. Jolleys (1992) in a national study found that many doctors felt their knowledge and training in the management of incontinence to be inadequate and many felt unable to satisfactorily manage and advise incontinence sufferers [19]. These findings may explain this erroneous advice.

Although older women present later for the assessment and treatment of urinary problems, there is insufficient evidence to support the assumption that their urinary symptoms are less troublesome. It is possible that in the study by Norton et al (1988) the earlier presentation of younger women reflects a greater knowledge about incontinence and its treatment as neither the symptom severity nor diagnosis affected presentation to the same degree [3]. It is also possible that urinary incontinence may affect the young and old differently. Longevity of suffering however undoubtedly results in a modification of lifestyle and adaptive change and it is likely that this too plays a major role in determining the quality of life impairment of sufferers. It is conceivable that young patients are more often able to modify their lifestyle and cope with physical disability than their older counterparts.

Little is therefore known about the effect of age on the subjective severity of urinary incontinence. Although it is likely that the young and old respond differently to

incontinence and that young patients are now better educated and less likely to tolerate this unacceptable departure from health than their older counterparts, these issues have never been adequately resolved.

HISTORICAL PERSPECTIVES
'QUALITY OF LIFE', WHAT IS TO BE MEASURED?

There is no consensus definition of quality of life or indeed subjective health status. Subjective health status or health related quality of life has come to mean a combination of patient assessed measures of health including physical function, social function, emotional or mental state, burden of symptoms and sense of wellbeing. Health related quality of life (HRQL) is a multidimensional construct that refers to an individual's perception of their state of health or disease and its subsequent treatment. Primary domains of HRQL include physical, psychological and social functioning, overall life satisfaction/wellbeing and perceptions of health status. Secondary domains include somatic sensations (symptoms), sleep disturbance, intimacy and sexual functioning and personal productivity (e.g. household, occupational, volunteer or community activities). The term is influenced by a broad spectrum of human experiences including diseases, accidents, treatments, interpersonal relationships and social support. Until relatively recently however, the severity of physical conditions and the results of treatment were measured in terms of death, disability or cure. It is however recognised that a patient's quality of life and psychosocial adjustment to illness are equally important as the status of their physical disease and the success of treatment can no longer be measured in terms of clinical parameters alone (table 3.1).

Dimensions of interest in Quality of life assessment
• Physical function : e.g. mobility, self care, exercise
• Emotional function : e.g. depression, anxiety, worry
• Social function : e.g. intimacy, social support, social contact, leisure activities
• Role performance : e.g. work, housework, shopping
• Pain
• Sleep / fatigue
• Disease specific symptoms

Table 3.1 The major dimensions of interest in QoL assessment.

APPLICATIONS OF QUALITY OF LIFE MEASURES

QoL questionnaires have many different applications (Table 3.2). QoL data have been shown to be better than conventional measures for the prediction of long term outcome in certain medical conditions. QoL measures for example have been shown to more accurately predict morbidity and mortality for patients with rheumatoid arthritis than conventional clinical parameters [20 21].

Applications of quality of life measures
• Screening and monitoring for psychosocial problems in individual patient care
• Population surveys of perceived health problems
• Medical audit
• Outcome measures in health services or evaluation research
• Clinical trials
• Cost utility analysis
• An adjunct to the clinical interview.

Table 3.2 The applications of quality of life measures.

SUMMARY

Over the last few decades, interest in the incorporation of patient assessed health status measures into the evaluation of medical care has increased. Several studies have shown that clinicians' and patients' judgements of quality of life differ substantially. This has increased recognition of the patient's view as central to the assessment of disease severity and evaluation of medical care. Functional status and well being are both highly valued by patients and are therefore essential outcome measures. This view has brought with it a multitude of approaches for the measurement of subjective well being. In an attempt to understand the plight of the incontinent population and the efficacy of our therapeutic interventions, quality of life assessment is however intuitively appealing. Not only would it allow us to quantify the distress caused by this condition but also enable us to understand how lives are affected, adaptive changes are made and what are the benefits of therapeutic intervention. As the primary goal in health care is to maximise function in everyday life and to achieve the highest possible level of well being for patients, some method by which to assess this goal is required. As outcome measures these would be of

great benefit when comparing treatments such as aids to continence with little apparent difference in clinical outcome but, where by methodology or limitation of side effects, they confer benefit over standard and accepted techniques. Generic and disease specific quality of life questionnaires and their use will be elaborated in the chapter on outcome measures.

References

[1]Thomas T.M., Plymat K.R., Blannin J, Meade T.W. Prevalence of urinary incontinence. Br Med J. 1980, 281: 1243-1245.

[2] Herzog A, Fultz N. Epidemiology of urinary incontinence: prevalence, incidence and correlates in community populations. Urology 1990;36(supp):2-10.

[3] Norton P, MacDonald, Sedgwick P, Stanton SL. Distress and delay associated with urinary incontinence, frequency and urgency in women. BMJ 1988;297:1187-1189.

[4] MacCauley A, Stern R, Holmes D, Stanton S. Micturition and the mind: Psychological factors in the aetiology and treatment of urinary symptoms in women. BMJ 1987;294:540-3.

[5] Ouslander J. Causes, assessment and treatment of incontinence in the elderly. Urology 1990;36(Suppl):25-35.

[6]Moore K.H., Richmond D.H., Sutherst J.R., Manasse P. One shot biofeedback in relation to psychoneurotic status and treatment response in detrusor instability. Neurourol Urodynam, 1992. 11, (4) 365-6.

[7] Kelleher C.J., Cardozo L.D. Sex and the bladder. Sexual and marital therapy. 1993, 8 (3) 231-241.

[8]Sutherst J.R. Sexual dysfunction and urinary incontinence. Br J Obstet Gynaecol 1979, 86: 387.

[9] HuT, Gabelko K, McCormick K et al. Clinical guideline and cost implications – the case of stress incontinence. Geriatr Nephrol Urol 1994; 4:85-91.

[10] Ekelund P, Grimby A, Milsom I. Urinary incontinence: social and financial costs high. BMJ 1993;306:1344.

[11] A report of the Royal college of Physicians. Incontinence, causes, management and provision of services, May 1995.

[12] CEST. Advanced medical textiles, London: Centre for Exploitation of Science and Technology, 1991.

[13] Department of Health. Community Services Division. An agenda for action on continence services. London: Department of Health 1991.

[14]Ouslander J.G., Kane R. L. The cost of urinary incontinence in nursing homes. Med Care, 1983, 22: 69.

[15]Giorup T., Hendriksen C., Lund E., Stromgard E. Is growing old a disease? A study of the attitudes of elderly people to physical symptoms. J Chron Dis 1987, 40 (12) :1095-1098. .

[16]Norton P.A., MacDonald L.D., Sedgwick P.M., Stanton S.L. Distress and delay associated with urinary incontinence, frequency and urgency in women. Br Med J, 1988, 297: 1187-1189.

[17]Mitteness L.S. So what do you expect when you're 85? Urinary incontinence in later life. Research in the Sociology of health care: vol 6. The experience and management of chronic iliness. Greenwich, Conn JAI press 1987, 177-219.

[18]Simmons J. Does incontinence affect your client's self concept? J Geronti Nurs. 1985, 11(6): 37 1.

[19] Jolleys J, Wilson J, Continence promotion in primary care- A national survey. Proceedings of the International Continence Society, 22nd annual meeting, Halifax, Canada. Neurourol Urodynam, 1992, 11. 4: 362-3.

[20]Wolfe F., Cathey M. (1991) The assessment and prediction of functional disability in rheumatoid arthritis. J Rheumatol, 1991, 1 8; 1298-1306.

[21] Leigh P, Fries J. Mortality predictors among 263 patients with rheumatoid arthritis. J Rheumatol 1991. 18: 1307-1312.1991

CHAPTER FOUR

REVIEW OF THE LITERATURE ON CONTINENCE DEVICES AND AIDS

REVIEW OF THE LITERATURE
ON CONTINENCE DEVICES AND AIDS

Impressions about individual conditions such as urinary incontinence – how common they are, what course it follows, how successful treatment is – are largely formed on the basis of clinical experience. Such a perspective is inevitably too restricted to be used to draw general conclusions. Before undertaking to provide a new service such as the use of continence devices or making adjustments to existing services concerned with continence aids, those involved with the management of female urinary incontinence must have an accurate picture of the safety and efficacy of such devices. There is no single source which provides all the information needed on continence devices. We can piece together information from different sources, the different types of devices with a common purpose and to which differing levels of importance are attached so as to gain a composite picture. I have looked at information and data collected and analysed in other studies describing the results of the Reliance and FemAssist and other continence devices as a valuable source to measure the clinical value of these aids to continence. This will also permit interpretation of the results of this trial in relation to the findings of other authors experimenting with the same or similar aids to continence.

PRODUCTS FOR INCONTINENCE

In the directing of continence and toileting aids provided by the Association for Continence Advice over 3,000 products are marketed by over 100 companies[1]. Cottenden (1991) in a review of aids and appliances found that there is very little research on which to base decisions on the choice of products and of the few trials which have been published, a high proportion are methodologically unsound [2].

HISTORICAL PERSPECTIVE

For centuries women have relied upon mechanical devices to control urinary leakage. Court ladies at Versailles had strategically placed Limoges porcelain "gravy boats" hidden under their elaborate gowns [3]. Edwards (1975) reported that ancient Egyptian papyrus writings made reference to the use of external urine continence devices for

women [4]. Edwards also noted that Hypocrites suggested inserting a finger into the vagina to support a defective bladder neck mechanism and thus prevent incontinence. Female devices were often occlusive and designed as a gold phallus-type structure which was placed intra-vaginally and potentially relieved stress incontinence. Continuous wear devices were probably not considered until rubber was manufactured. Early continuous-wear devices were in the shape of a wide-neck rubber funnel that completely enclosed the vulva and was firmly attached to the body with a support belt. Some had flannel walls and a steel spring wire which prevented the device from collapsing from the pressure of the thighs [5]. Modifications were made to the funnel so as to prevent crushing when the wearer was seated and to prevent excessive pressure on the perineum.

Since the discovery of rubber, many materials have been invented that tend to be both non-irritating and rugged. Medical grade latex and silicone have FDA approval for human use. They are soft and durable. These products are cost effective and have been used for condoms and indwelling catheters. Beyond biocompatability concerns, material selection is generally a manufacturing issue.

APPLICATION

Continence aids tend to be applied either over the labia or placed between the labia minora. Either form may be designed with or without a vaginal locator to help position and secure the device.

Terman (1964) and Fielding and Wells (1975) described devices that cover the labia and have a vaginal locator [6 7]. Terman invented a single-piece structure device that has a front section covering the labia and lower abdomen, a urine-receiving section and flexible drainage. It curves posteriorly to insert into the vagina. Fielding and Wells, who are nurses, tested a cup-shaped device that covers the labia, had a vaginal locator and was held in place by a panty girdle with a Velcro crotch opening (Figure 4.1).

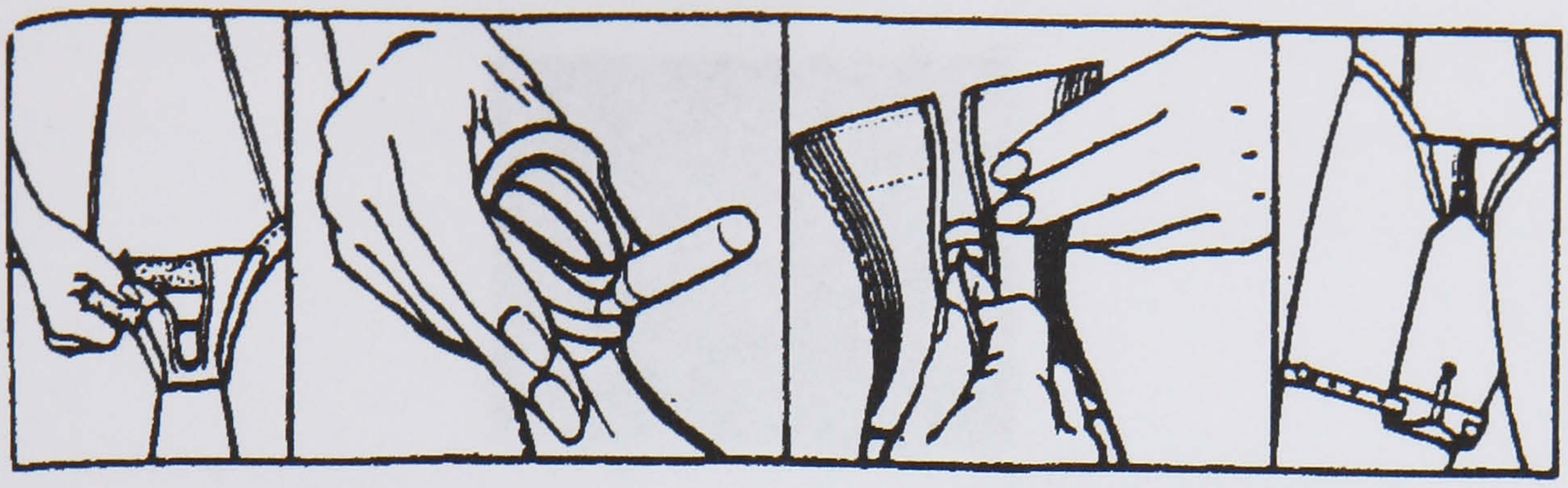


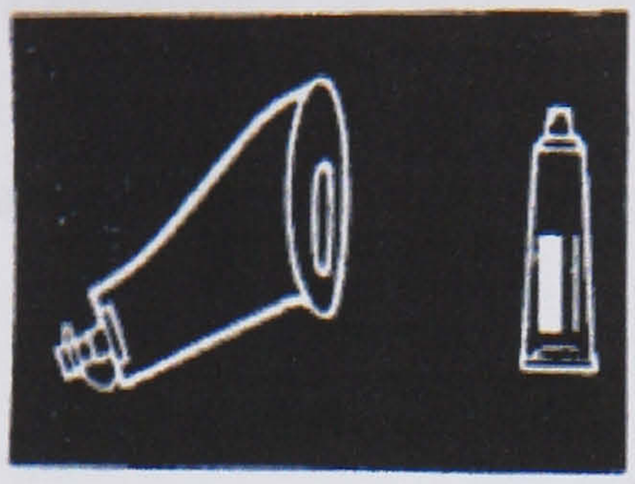
Figure 4.1 Fielding and Wells device (1975)

These products would be relatively easy to apply since only the vagina must be located, not the urethra. Twelve elderly patients wore the device for 2 to 10 days and ill-defined success in urine collection was reported to range from 0 to 92 per cent of applications. During testing, Fielding and Wells (1975) noted that the device caused pressure markings and erosion of the soft tissue of the vulva. The nursing staff expressed reservations about the appearance of the device and the placement of the vaginal locator. The authors concluded that the device was unsuitable for elderly patients.

The Hollister Female Urinary Pouch (1986) is a one-piece system that encompasses the vulva but lacks a vaginal locator [8] (Figure 4.2). The mons pubis area is shaved, cleaned and dried. The genital area where the pouch will be applied is then wiped with a skin gel wipe. The vulval opening is measured and the synthetic skin barrier cut to fit the woman.

The barrier has adhesive properties and adheres to the labia majora and perineum. An adhesive tape helps to further secure it. The drainage pouch may be attached to drainage tubing.

Other devices are positioned between the labia minora to surround the urethra. Breece's (1965) patent includes a circular ring which is placed between the labia minora to encompass the urethra [9]. To help contain urine leakage, the ring is encased in a triangular support piece placed over the entire lower pubic area.



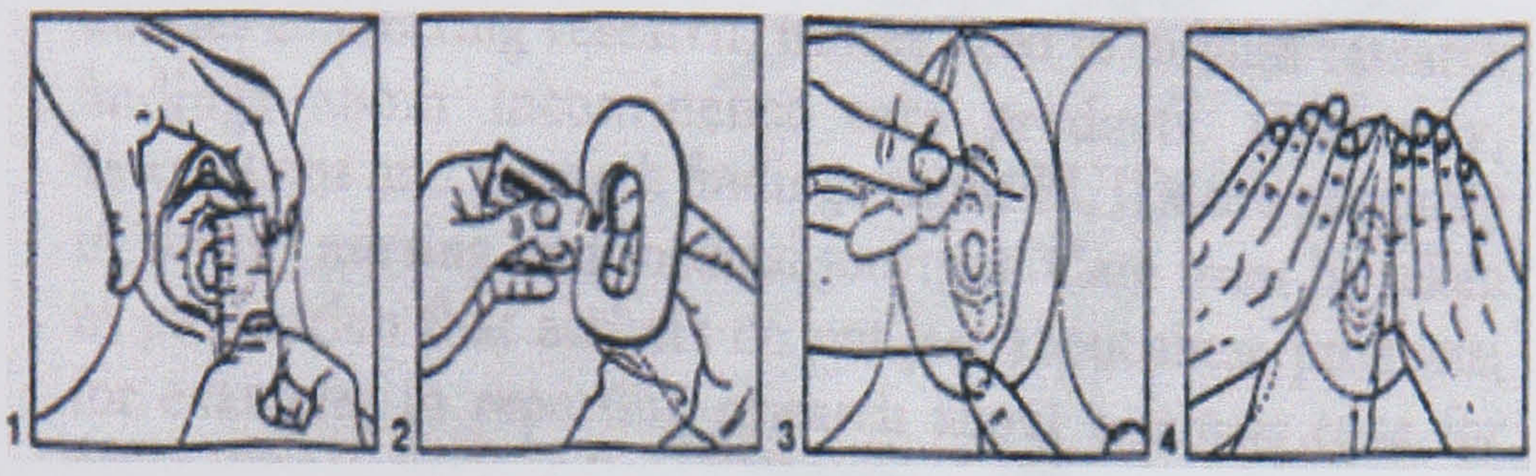


Figure 4.2 The Hollister Female Urinary Pouch (1986)

FEMEX, (1982) was manufactured and marketed for a short time [10]. FEMEX, a small flexible umbrella-shaped device, was positioned midway between the clitoris and vaginal opening to surround the urethra and was held in place by a liquid adhesive for up to 24 hours. Women were to wear undergarments, cutting a small hole in the crotch and threading the catheter drainage tubing through it.

MISSTIQUE (Michaud 1981) is ovoid and also fits between the labia minora [11]. It is held in place by a silicone sealant and suction (Fig. 4.3). Suction is created by a vented one-way valve that allows urine to drain and prevents the return flow of urine from the collection unit. Women may purchase panties and panty liners with holes to accommodate the drainage tube.

Figure 4.3 MISSTIQUE (Michaud 1981)

A modification of the placement of a device between the labia minora was made from Blackmon's patent (1984) [12]. The Blackmon device is placed between the labia majora; the labia minora are positioned inside the drainage opening (Figure 4.4)).

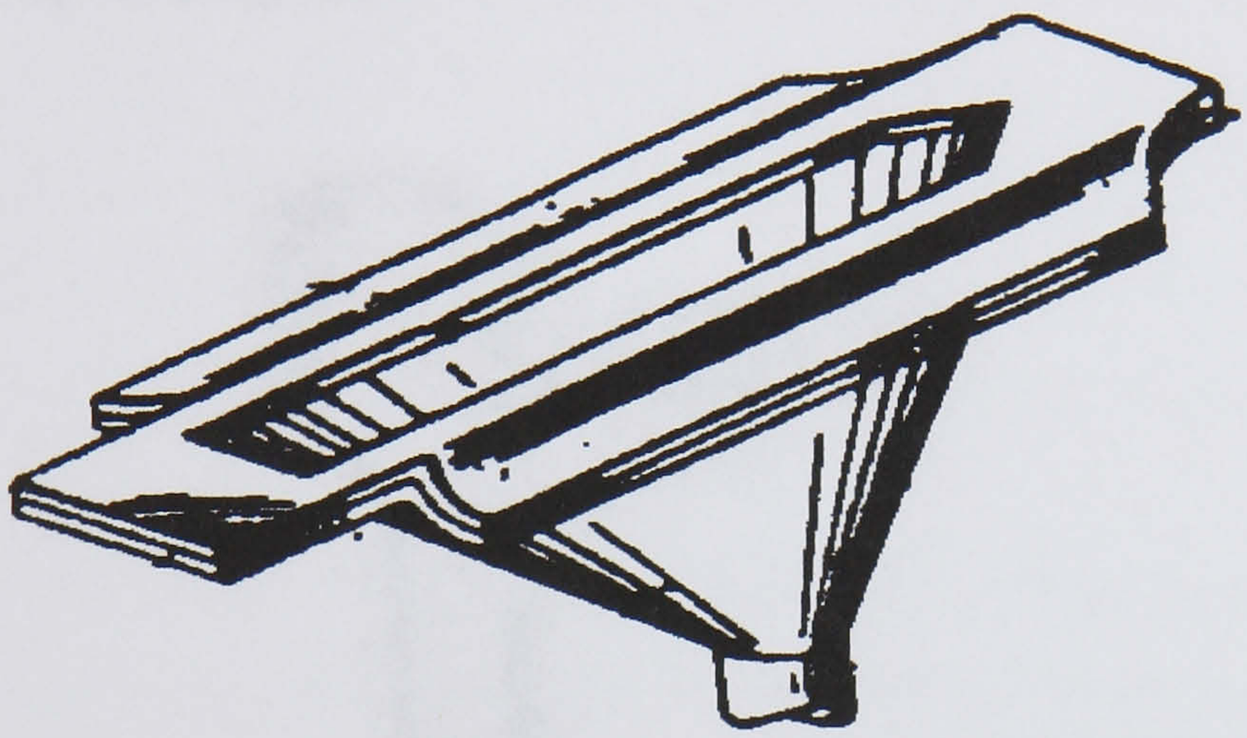


Figure 4.4 Blackmon's patent (1984)

Some devices placed between the labia also include a vaginal insert. This is true of the earliest U.S. patent awarded for a continence aid. The Williams (1949) patent consisted of a cylindrical hollow tube that was positioned into the vagina and a faceplate that rested against the labia (Figure 4.5) [13]. Urine was to flow back to the tube and drain to a collection bag. The faceplate was held in place by a suspensor belt to the waist, much like Breece's.

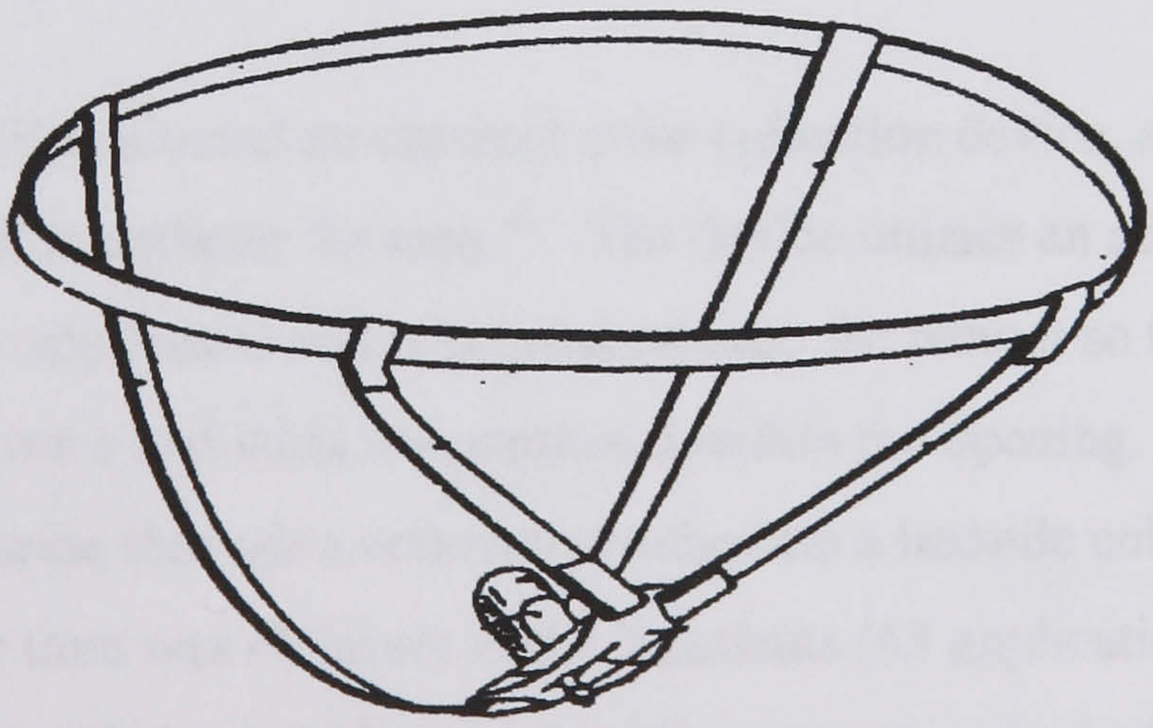


Figure 4.5 The Williams device (1949)

Michaud (1981), working for National Aeronautics and Space Administration, received a patent for a device that fit between the labia and had a vaginal insert to help position it and prevent urine flow into the vagina (Figure 4.6). The device included a body of wicking material to absorb urine before leakage and thus move urine away from the skin. This patent was received when women were actively involved in the space program.

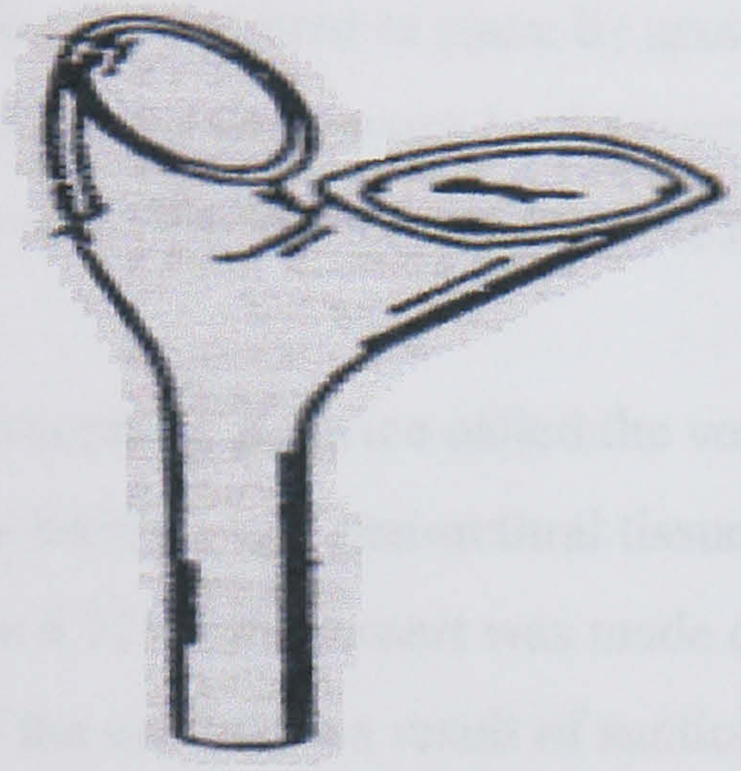


Figure 4.6 Michaud device (1981)

Products placed between the labia require that a woman has some degree of lower limb flexibility since the urethra must be located for proper placement. A woman's dexterity, vision and comfort in touching the genitalia will affect its usability. Its use also depends on health care personnel to teach the woman the necessary skills to place the device correctly.

Johnson et al (1989) evaluated an external urine collection device, analogous in function to the condom catheter for men [14]. The device utilises an adhesive similar to that used on ostomy appliances and is positioned onto the patient so that the urethral meatus, vaginal introitus and labia are contained within the opening. The device is designed to funnel urine through a connecting tube into a bedside collector. The median device wear time was 48 hours in the 7 patients (63 applications of the device for 125 patient days). Through 24 hours of continuous use, only 8 of 63 devices (13%) leaked urine and only 2 of those were in sufficient quantity to require replacement. At 48 hours, only 9 of 63 devices (14%) required replacement due to unacceptable urine leakage.

A continence device should be suitable for both day and night use as well as for bedfast, sedentary and active women. Some devices have included suction equipment, which may limit use with very active women. Urovac (Keane, 1971) for example, consisted of a suction head that was placed over the labia majora, a corrugated suction tube that ran from the suction head to the urine container and a clear plastic breather tube that provided a constant flow of air into the suction head so that the vacuum applied to the tissue remained very low [15]. The airflow also dried the tissue after urination. Urovac was held in place by accurately fitted, light elastic shoulder straps. It was designed to be worn by the woman in bed to remove postural diuresis, thus promoting rest. The device, however, is not commercially available.

Crowley et al (1971) introduced a device called the vestibulo-vaginal insert. It used suction to produce a seal between the periurethral tissues and the suction disc of the collection device (Figure 4.7) [16]. The insert was made of inert plastic. To prevent irritation and oedema of the urethra as a result of suction, a fine protective netting covered the suction disc. The vaginal piece of the device had a canal to drain secretions. Principles of physics governed the suction in the device's inverted water bottles.

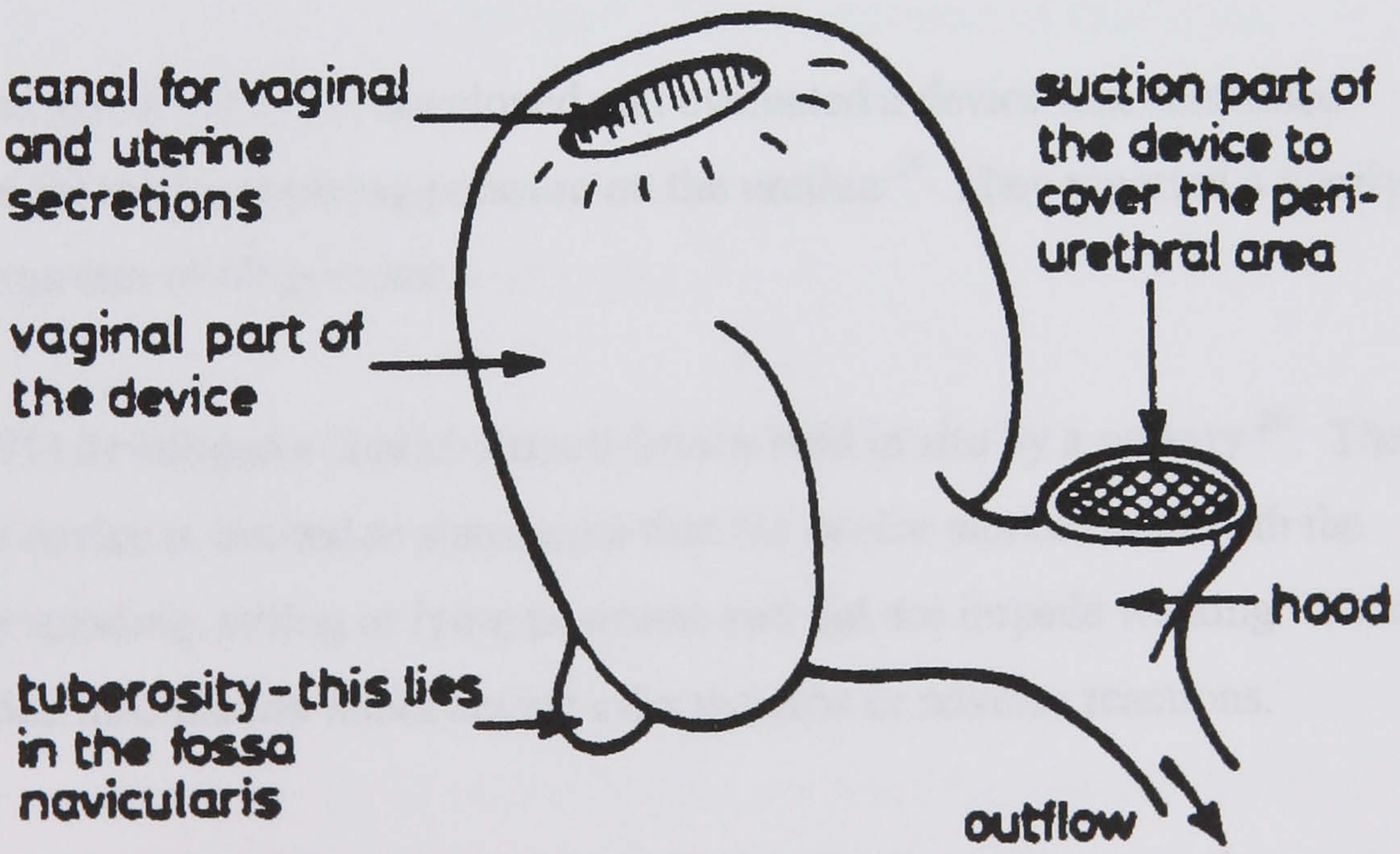


Figure 4.7 The vestibulo-vaginal insert (Crowley et al 1971)

The device was tested on 54 women, aged 15 to 70, who had normal bladder function and had delivered at least one child. The women wore white briefs that were

inspected for leakage of urine. Three individuals had leakage of 2-3ml of urine; the other women were completely dry after urinating. The number of voidings varied from 1 to over 10 per individual; the average urine excreted was 250 ml. The authors reported that there was no periurethral oedema or infection. They stated that the device was comfortable to wear, unobtrusive and free from side effects; in addition, some women were able to sit, stand and walk with it in place.

Patents for devices generally state that it can be worn by active or bedfast women unless the product is designed as a female urinal. Female urinals are held in place and lack a support belt or adhesive. For example, Hall (1976) patented a disposable female urinal that enabled a woman to void in a lying or sitting position [17]. The device resembled an open duck's bill. It was placed between the labia with one sup-like projection positioned in the vagina; the other, around the urethra. The drainage receptacle was attached.

Li (1977) invented Sanifem, a trough-shaped device to facilitate urination when a woman is "exposed to weather, insects or unsure footing" as an "answer to wilderness restroom problems" [18]. There are also female urinals that resemble male urinals, for example, Viscots "Millie" the Urinal.

Edwards and Malvern (1973) developed and evaluated a device that controlled urinary incontinence by applying pressure on the urethra.[19] They reported a poorly defined success rate of 69 per cent.

Linden (1971) developed a funnel-shaped device held in situ by a pessary [20]. The report of this device is limited to statements that the device worked well with the patient in the standing, sitting or lying positions and did not impede walking. There was no detailed information about device effectiveness or adverse reactions.

To our knowledge none of the devices described in the literature currently are available commercially. Results from this preliminary evaluation suggest that external urinary incontinence devices held in situ by adhesive similar to that used on ostomy appliances may provide a useful alternative to other methods of long-term management of urinary incontinence in non ambulatory women. Additional studies

for longer, more clinically relevant periods appear to be warranted. Once long-term efficacy is established the impact of external device use can be investigated.

PADS

For some women the provision of incontinence aids will be necessary. Absorbent incontinence products are not prescribable and are therefore obtained through the community nursing services. The cheapest pads are usually the least effective and often prove to be a more costly long-term option. There are many different types of product available and a careful assessment of both the severity of the incontinence and the needs of the patient are required prior to selecting the most appropriate pads. Pads are usually in close fitting pants but in cases of slight incontinence, the patient's own underwear is adequate and often more comfortable.

Patients living in their own or residential homes who require absorbent products may be supplied by their Health Authority (HA). The HA has discretionary powers to provide "in the light of local needs and circumstances". Each may determine its own budget and criteria for supply. In practice there are great variations between areas. HAs must supply to people in residential homes on the same basis as they supply to people in their own homes. Social services are responsible for purchasing pads for people they have placed in nursing homes [21]. The Department of Health has suggested that a good service may actually decrease costs and recommends that there should be no changes in supply without an assured alternative being in place, so as not to leave vulnerable individuals without supply [22].

CATHETERS, COLLECTING DEVICES AND BED ALARMS

Some women are managed in the community with either an indwelling urethral or suprapubic catheter or by means of clean intermittent self-catheterization (CISC). The most common indications for catheterization are acute and chronic retention, postoperative bladder drainage, the neuropathic bladder and intractable urinary incontinence (Figure 4.8).

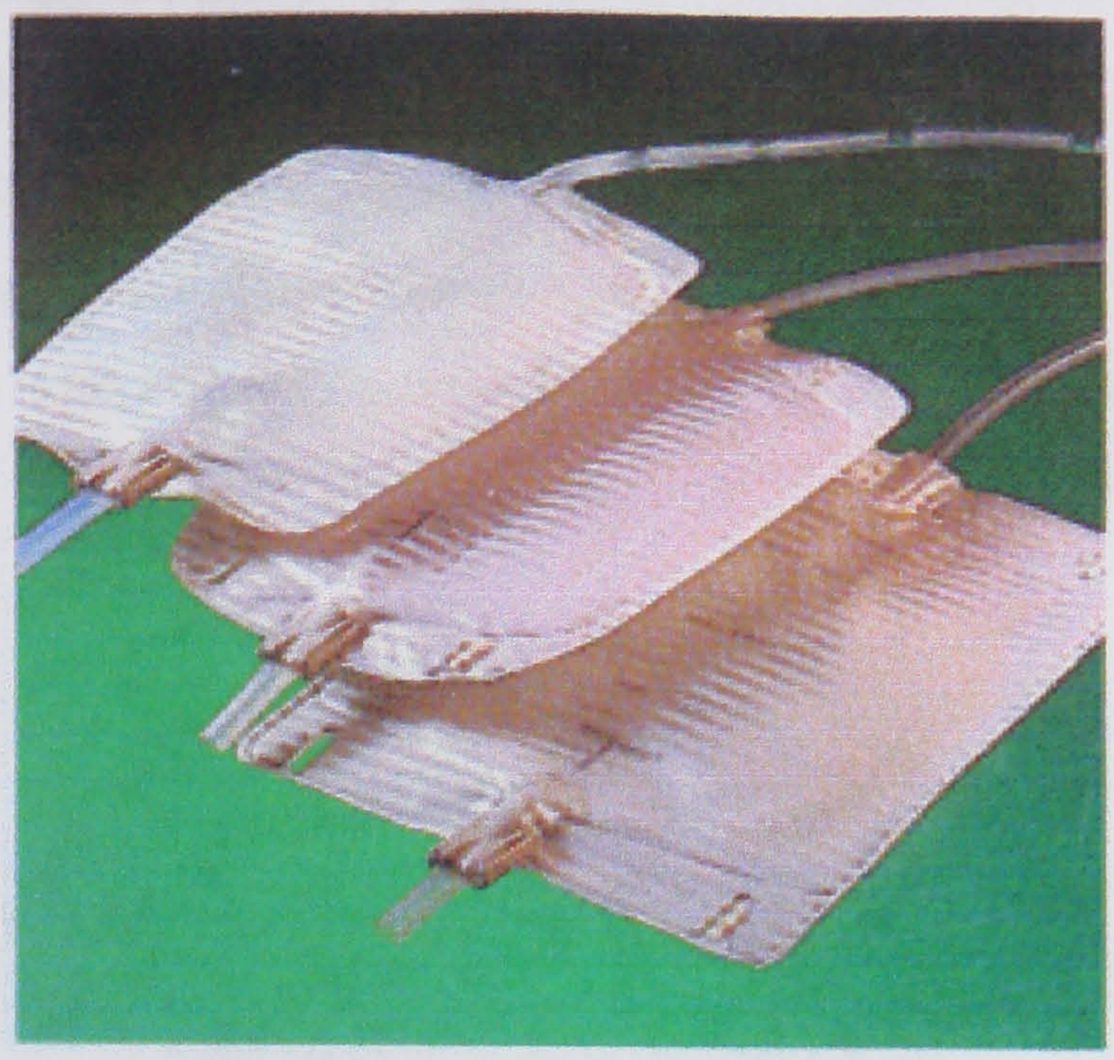


Figure 4.8 Urine bags

An indwelling urethral or suprapubic catheter is the most commonly used method. Long-term urethral catheterization has the drawback of discomfort, urethral trauma and a high incidence of symptomatic urinary tract infection by contamination from perineal flora. Suprapubic catheterization is often more comfortable, particularly in patients who are sexually active and the lower density of bacteria on the anterior abdominal wall results in fewer significant urinary tract infections [23]. In the short term catheterised patient clamping of the suprapubic catheter allows voiding per urethram, an advantage not shared by the urethral catheter. Women must be motivated and often have to catheterise themselves despite major neurological deficits, lack of perineal sensation, intention tremor and even blindness. Only through correct patient selection and detailed explanation of the technique is it likely to be effective. Most women can be taught as outpatients by a doctor or at home by a continence advisor or suitably trained nurse. They should be given clearly illustrated instructions on both catheter insertion and care. Sterility is not essential but women should be instructed to wash their hands and then wash or wipe clean the area around their urethral orifice prior to catheter insertion. The catheter should be washed in tap water and then either boiled for thirty seconds or left immersed in 0.016% sodium hypochlorite solution.

Plastic "lo fric" catheters are more rigid and easy to pass and last for about a month if kept in hypochlorite solution. Stainless steel catheters will last for years and are easily sterilised in a domestic oven. Severe adverse effects are uncommon although bleeding, false passage formation, urethral stricture and bladder calculi can occur. Overall, the technique is surprisingly acceptable and relatively free from side effects (Figure 4.9).

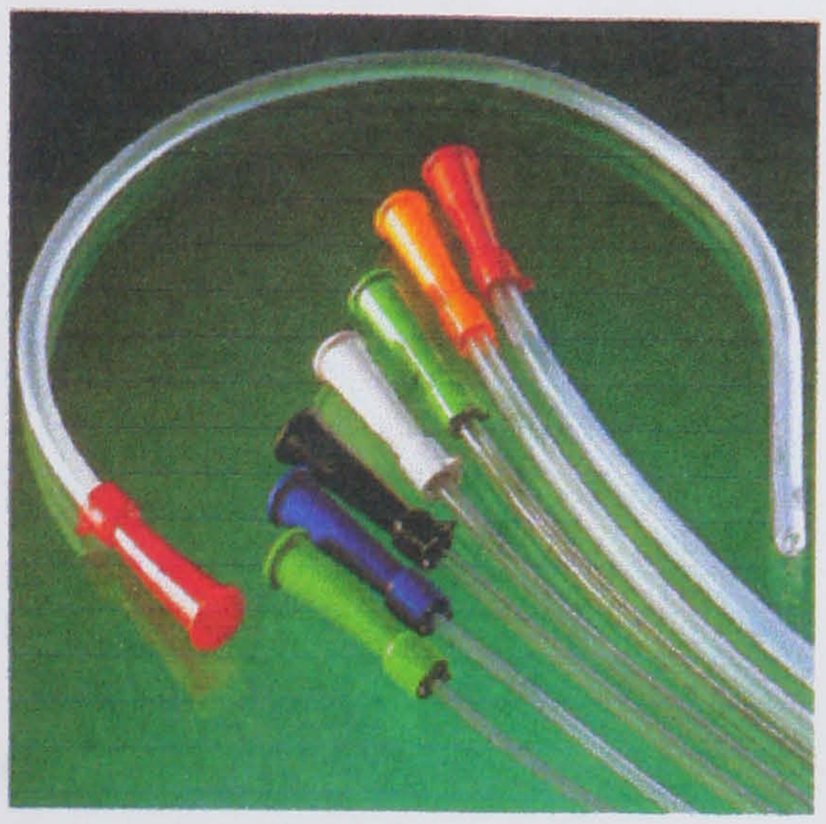


Figure 4.9 Conveen EasiCath, a disposable catheter with a specially treated surface for better comfort in CISC.

Whichever method is adopted, close supervision by a suitable trained district nurse or specialist continence advisor is required to avoid complications.
For incontinent women, the design and attachment of external devices capable of collecting urine has been a continuing problem, although the incidence of bacteriuria appears to be even lower than that found with urethral catheters.

ANAL PLUGS

Disorders involving the multiple systems in the pelvic floor are common. Women who suffer urinary dysfunction may also suffer faecal incontinence, as there is likely a common pathophysiology such as neuromuscular abnormalities and connective tissue damage. Products are also available for this condition and an anal plug has been described. This is illustrated below (Figure 4.10).

Figure 4.10 Anal plugs.

CONTRACEPTIVE DIAPHRAM

For many centuries numerous kinds of mechanical devices have been used for the control of incontinence in women. Among these non-surgical modalities, vaginal pessaries and contraceptive diaphragms have been used commonly not only to relieve vaginal wall prolapse and uterine descent but also symptoms of stress incontinence [24]. Contraceptive diaphragms can support the urethrovesical junction. Despite frequent relief of urinary incontinence observed with the use of the vaginal pessary, the manner in which a pessary restores continence is poorly understood. With a diaphragm in place, studies have shown a significant reduction in the mean peak urine flow rate [25]. These studies have also demonstrated that the degree of outflow obstruction however is of a relatively small magnitude. Urethral profilometry with the diaphragm in place caused a marked increase in maximum urethral closure pressure.

Suarez et al (1991) have used standard contraceptive diaphragms successfully in the management of women with stress incontinence [26]. Realini and Walters (1990) performed a similar trial and found that diaphragms could produce a 40% response rate based on improvement in the outcome measures of pad weight test (PWT) gains, decreased number of weekly leakage episodes on urinary diary and subjective improvement of symptoms [27]. The studies by Realini and Walters (1990) and Suarez et al (1991) did not test for the treatment of exercise induced incontinence and most

studies have not examined the activity levels of women when reporting treatment success. Success rates may be lower if women participated in more provocative activities. In a prospective randomised study, Nygaard (1995) assessed the efficacy of two mechanical devices, the Hodge pessary and a tampon in the management of exercise-induced incontinence [28]. Eighteen women participated in 3 separate standardised 40-minute aerobics sessions. One group used Hodge pessaries, the second group used Tampax super tampons and the third group used no device. Assessments were made of urinary leakage based on pad weight gain at the end of the exercise session. All women voided and then drank 240 ml of water one hour before exercising. Four women remained continent during the control session (no device) despite reporting stress incontinence and a positive cough stress test at initial evaluation. Table 4.1 summarises the results for the PWT gains for the 14 women with incontinence during exercise.

Efficacy of mechanical devices (Hodge pessary & Super tampon)		
Groups	**Pad weight gain(grams) Before use**	**Pad weight gain(grams) After use**
	Mean(range)	Mean(range)
Control	45.3 (4.1-140)	**?**
Hodge Pessary	36.4 (0.2-256)	**?**
Tampon	31.0 (0.7-137)	**?**

Table 4.1 Pad weight gains without devices and with each of the two devices (n = 14) during standardised exercises. [Nygaard (1995)]

Table 4.2 shows the success of each device in dealing with varying degrees of incontinence and with incontinence in general.

Efficacy of each method		
Urine loss during control session	**Continent with pessary**	**Continent with Tampon**
<15g	57%	86%
>50g	14%	29%
All women	36%	58%

Table 4.2 Success of each device in dealing with varying degrees of incontinence and with incontinence in general (n = 14). [Nygaard (1995)].

The devices were most effective in women with mild degrees of incontinence. Interestingly, the severity of exercise incontinence did not correlate well with the severity as judged by the cough stress test performed with a comfortably full bladder.

Overall comfort was reasonable with each device, but those who found the tampon uncomfortable (6) were different from women who thought the pessary was uncomfortable (4). The study did not address whether women can easily void with either device. A pad weight gain of <4.0g was considered to indicate clinical continence. This seems quite generous. Women can initiate treatment on their own if using a tampon which is an advantage over a pessary. However, the Hodge pessary is reusable and this is a significant cost saving. The precise aetiology of incontinence during exercise is unknown, and failure of the devices may be due to detrusor instability. However these devices are still useful without formal urodynamics

SMITH-HODGE PESSARY

The Smith Hodge pessary when used during urodynamic testing has also been shown to be simple, inexpensive and reliable for the evaluation of urinary incontinence (Figure 4.11). It aids in the pre-operative selection of incontinent women suitable for continence surgery by simulating the anatomic results of surgery for GSI and may help to predict the successful outcome of surgical therapy [29].

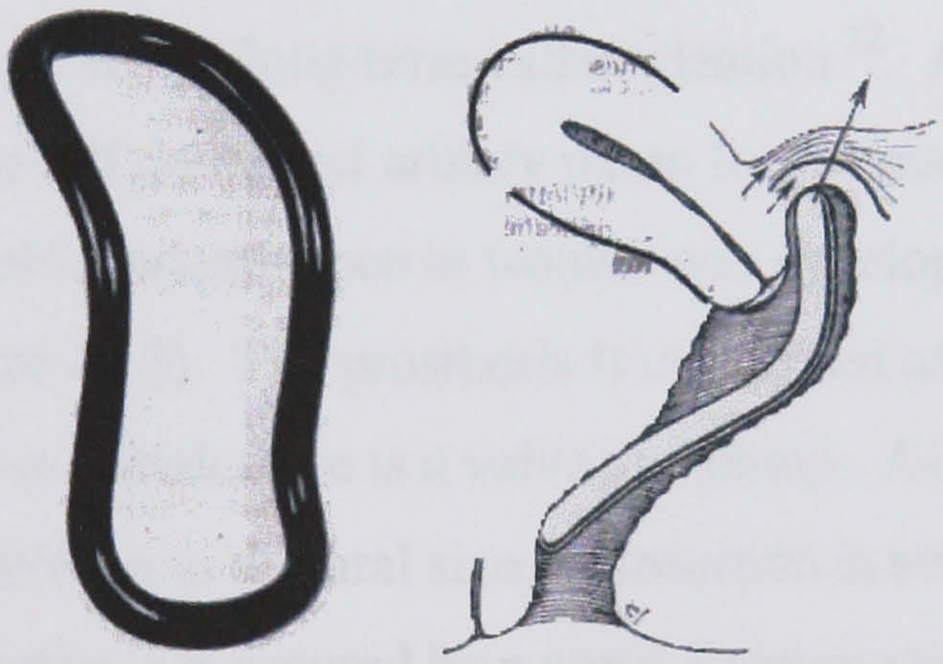


Figure 4.11 Hodge pessary

Bhatia et al (1983) investigated the urodynamic effects of a Hodge vaginal pessary in women with GSI [30]. Following placement of the vaginal pessary, detailed urodynamic studies were performed on 12 women with GSI. They demonstrated consistent and significant ($p<0.005$) increases in urethral functional length and urethral closure pressure under varying stressful conditions, when compared with pre-pessary studies. Clinically, 10 of the 12 women became continent with the device in place. There was no evidence of outlet obstruction based on uroflometry and pressure

flow studies. Post-pessary urodynamic alterations and Q-tip test changes provided an objective explanation that the vaginal pessary restored continence by stabilising the urethra and urethrovesical junction. This allowed proper pressure transmission and actively increased urethral resistance to escape of urine under resting and provocative conditions.

INCONTINENCE RING

Leong and Brubaker (1996) assessed the use of a modified intravaginal ring pessary to control leakage in women with stress incontinence [31]. Thirty-six women were recruited but 11 found the device unsatisfactory. Of the remainder, patient symptoms were controlled satisfactorily in 69.4% of cases. No objective data on outcome measures of the efficacy of the ring were reported.

A NEW INTRAURETHRAL SPHINCTER PROSTHESIS WITH A SELF CONTAINED URINARY PUMP

Devices have also been used successfully in women with chronic retention of urine as an alternative to intermittent self or long-term catheterization [32]. An intraurethral sphincter prosthesis with a self contained urinary pump for the management of the atonic bladder and intractable incontinence in women was developed and tested by Nativ et al (1997) [33] (Figure 4.12). The prosthesis is comprised of a short, self-retaining silicone catheter in which there is a valve and pump. Available in a range of lengths and diameters according to urethral size, its insertion is similar to that of a urethral catheter. The prosthesis is secured by a novel fixation method that has soft expandable silicone fins at the bladder neck and a flexible flange at the external meatus. A small hand-held control device activates it. To urinate, the activator is placed on the lower abdominal area and the "on" button is pressed, providing energy to the pump by a magnetic coupling method. Once activated, the valve opens and the pump rotates at a high speed, drawing urine from the bladder and pushing it forward, allowing the patient to "void" with a urine flow of 10 to 12ml/sec. When the bladder is completely evacuated the pumping ceases and the valve closes, restoring continence.

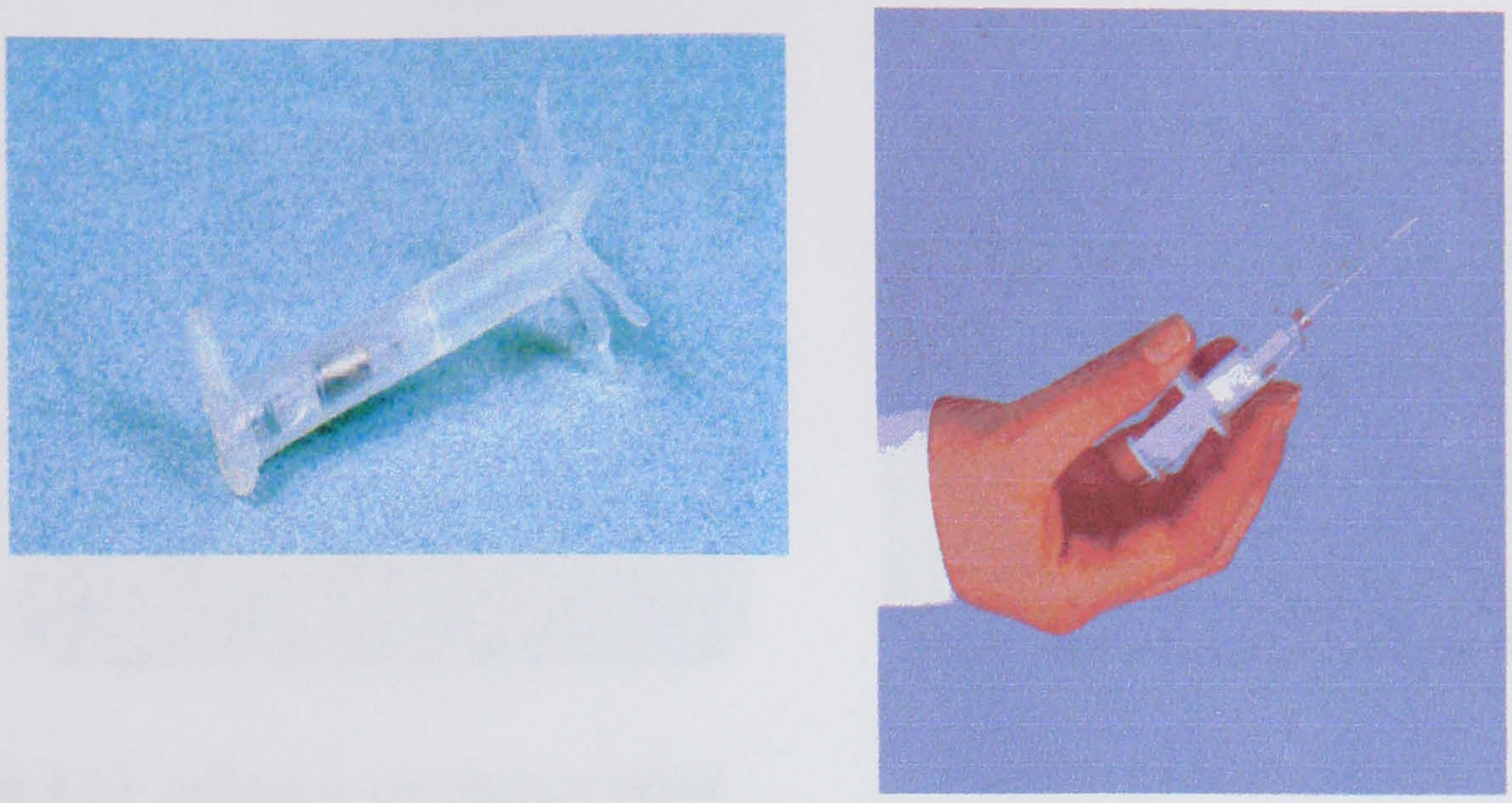


Figure 4.12 Intraurethral sphincter prosthesis with a self contained urinary pump.

The device was evaluated clinically in 17 women. Fifteen of the patients had a range of use of 2 weeks to 16 months during which they were dry and had complete bladder emptying. Two patients did not tolerate the device because of uninhibited detrusor contractions and, in both cases, it was removed without complication after 5 days.

ADHESIVE PATCH

North (1998) evaluated a disposable adhesive patch in the management of women with stress incontinence [34] (Figure 4.13). The device is formulated from polyurethane foam, backed with an adhesive made from poly-2-hydroxyethyl methacrylate and polyethylene. It is triangular in shape, with a protruding "fin" to facilitate placement and removal from between the inner labia. The device is designed to seal the urethral opening and prevent leakage utilising the adhesive.

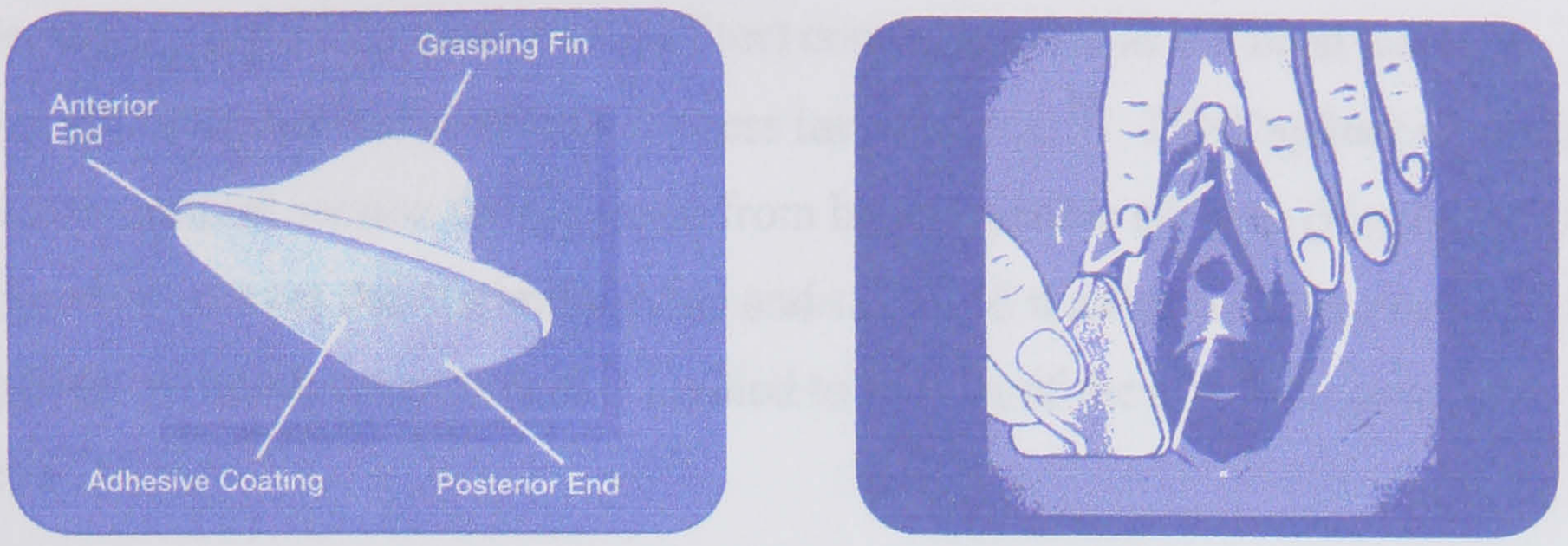


Figure 4.13 Adhesive continence patch.

Thirty-seven women used the device for 12 weeks. The study group included women with the primary symptom of mild to moderate stress incontinence. Overall leakage was reduced by 60% from 1.1 [± 0.3 SEM] grams/hour without the patch to 0.44 [± 0.11 SEM] g/hour while using the device ($p<0.05$). With the patch in place urinary diaries showed that the number of incontinence episodes per week decreased by 67%, from 13.3 [± 1.9 (SEM)] to 4.3 [± 0.9 (SEM)] leakage episodes per week ($p<0.05$).

Out of 201 urinalysis, only one was positive for leukocytes. Haemolysed blood was found in 30 specimens. No UTIs were recorded. The vestibular tissues showed an increase in the proportion of superficial cells during patch use. Vaginal microflora demonstrated no overall change.

Based on an incontinence impact questionnaire, device use was associated with a significant overall reduction in the impact of incontinence on quality of life ($p<0.05$), and many activities of daily living were made easier. The majority of women described the patch as easy to use and comfortable.

It is interesting to note that the urinary diaries showed significant improvement in the number of leakage episodes in the post-test control period when the patch was no longer used. The authors proposed that it acted as a form of biofeedback training increasing sensory awareness of the urethral musculature.

CAPSURE SHIELD

Another device called the CapSure (Re/Stor) continence shield has been tested by Bellin et al (1998) for the treatment of stress incontinence [35]. The CapSure device is a small extra-urethral suction device made from biocompatible silicone (Figure 4.14). When positioned over the urethral meatus and squeezed it adheres to the mucosa. A thin coating of petroleum ointment is applied to the rim of the device to improve adhesion.

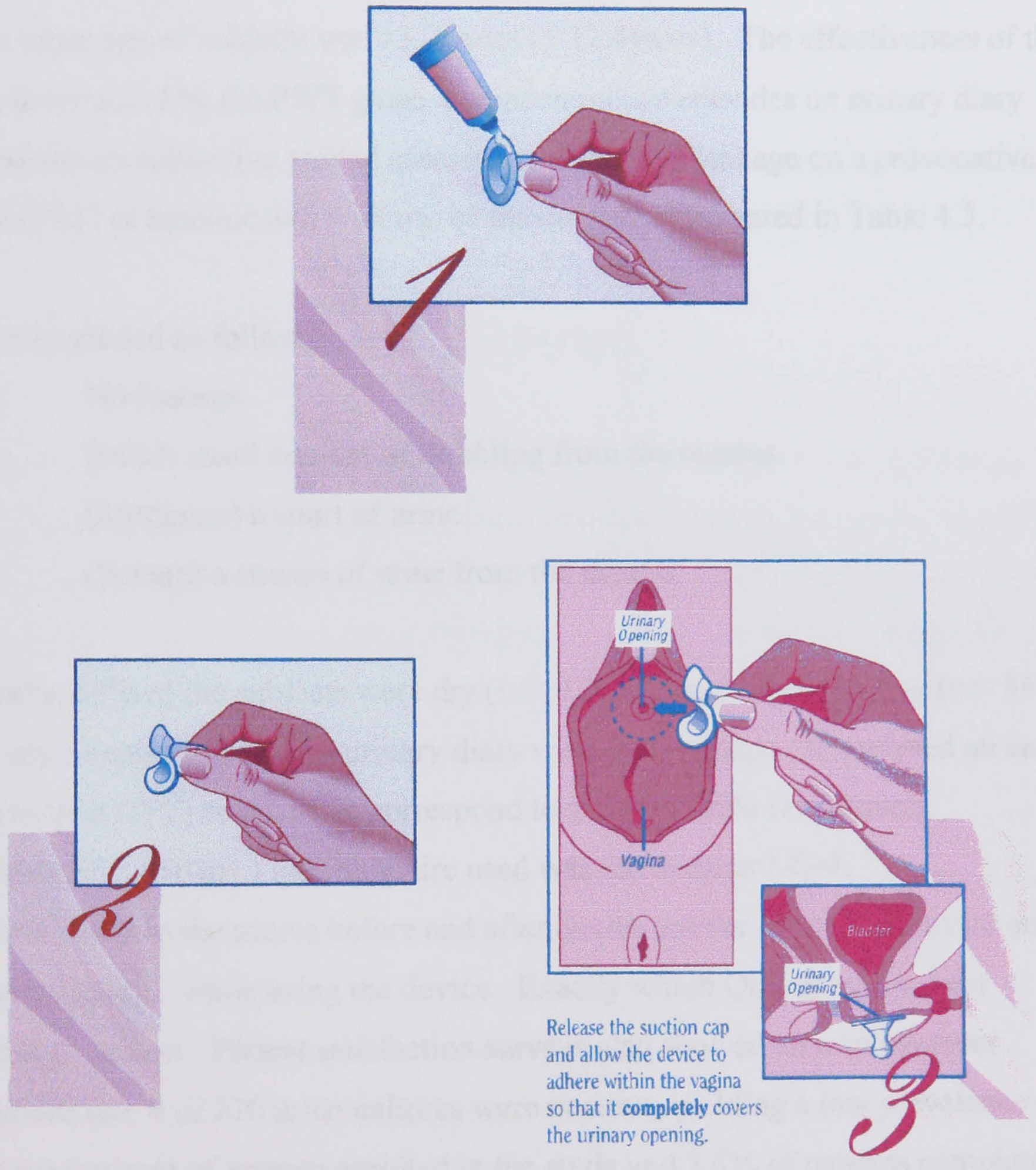


Figure 4.14 The CapSure (Re/Stor) continence shield and steps for application.

The device, like the FemAssist, is re-usable – subjects are instructed to wash the device with soap and water, rinse and dry thoroughly before each application. It was

advised that a new device be used every 2 weeks. Women with GSI were recruited to the 6-month study from 7 clinical centres in the USA. Efficacy outcome measures included a short PWT, a provocative stress test, incontinence diary, quality of life questionnaires and a satisfaction survey, performed prior to enrolment, while using the CapSure shield and after discontinuation of the device. One hundred women were enrolled but 84 completed the study. There were no real differences between those who completed the study and the "withdrawal group" based on the demographics, severity of incontinence and pad weight data. At enrolment the mean incontinence episodes on the diary for women completing the study was 3.36 per day (range 0.9-8.6). The mean age of subjects was 53.2 years (± 12.4years). The effectiveness of the device as determined by the PWT gains, the incontinence episodes on urinary diary and the examiners subjective graded assessment of urinary leakage on a provocative stress test (PST) at baseline and with use of the device is illustrated in Table 4.3.

The PST was graded as follows:

0 No leakage

1 (Mild) small amount of dribbling from the meatus

2 (Moderate) a spurt of urine

3 (Severe) a stream of urine from the meatus

By 12 weeks, 82% of the subjects were dry (</= 0.2g) on pad weight testing (n = 84) and 48% dry (0 episodes/day) on urinary diary with device usage. If analysed on an intention to treat (ITT) basis, these correspond to 69% and 40% respectively.

The Quality of Life (QoL) questionnaire used was the Wagner I-QoL [36]. Comparison between the scores before and after device use for 12 weeks showed an improvement in QoL while using the device. Exactly which QoL domains were improved was unclear. Patient satisfaction surveys also showed an improvement. During device use, 4 of 270 urine cultures were positive, yielding a low prevalence of 1.5%. Three per cent of women enrolled in the study and 3.5% of patients completing the study had positive urine cultures. None of the subjects withdrew because of a positive culture. Otherwise adverse events were few and required no therapeutic intervention. It is important to note that the PWT was not one recommended by the ICS. Thus it is difficult to interpret these PWT gains. The device was thought to

have a therapeutic effect as well since PWTs and incontinence episodes per day remained lower than baseline 6 weeks after discontinuing the trial.

Efficacy of CapSure shield					
Outcome Measure	Baseline N=100	Week 1 n=97	Week 4 n=88	Week 12 n=84	*Ave
PWT gain(g)					
Mean	6.67	0.24	0.11	0.19	0.18
Range	(0.55-25.9)	(0 –6.7)	(0 – 2.8)	(0 – 2.5)	(0 – 2.5)
Incontinence episodes					
Mean number/day	3.4	1.1	0.4	0.3	0.6
Range	(0.9-8.6)	(0 –8.2)	(0 – 4)	(0 – 2.7)	(0 – 3)

Table 4.3 Improvement in urine loss at baseline and during CapSure device use throughout the trial {Bellin et al (1998)}. *Ave = Average based on all data available for weeks 1, 4 and 12.

CONTINENCE CONTROL PAD

The continence control pad (CCP) is a small non-invasive adhesive pad (Advanced Surgical Instruments, San Clemente, Ca, USA) which is fitted by the patient over the external urethral meatus between micturitions. It is a hydrogel-coated contoured foam occlusive pad and the adhesive hydrogel sticks to wet skin with no loss of strength for up to 5 hours. The pad has a tapered end that is oriented towards the front of the patient and a blunt end that is oriented towards the vagina.

Eckford et al (1996) assessed the use of this pad in women with symptoms of stress incontinence [37]. Nineteen women [median age 47 years (range 36-72), median parity 2 (range 0 – 6)] completed the study. Assessment was made the week before and again after using the CCPs for 2 weeks by a review of symptoms, urinary diary kept for seven days and a pad weight test. In the week before the trial, a median of 4 sanitary pads were used per day (range 2 – 9). There was a significant decrease in the number of incontinence episodes per week ($p = 0.002$) with 3 women completely dry and 14 having fewer episodes of leakage and 2 having the same or an increased number of incontinence episodes. They defined success as a cessation or reduction in the number of incontinence episodes. Use of the CCP was associated with a cure or improvement in 17 women. There was also a significant decrease in the pad test

leakage (p = 0.002) with device use. The values for the median and range of pad weight gains were not stated so it is difficult to interpret whether these data are also clinically significant. Also the subjects were older and obese so the device may have been more difficult to put in place. No patient complained of urethral discomfort or experienced dysuria or haematuria. Table 4.4 shows complications encountered in the study.

Complications of the continence control pad	
Introital discomfort on placement	1
Introital discomfort on removing	2
Poor adherence to skin	4
Urinary infection	1
Urinary urgency/frequency	2

Table 4.4 Complications encountered in 19 women using the continence control pad. [Eckford et al (1996)]

CONVEEN CONTINENCE GUARD

Thyssen and Lose (1996) developed a disposable vaginal device (Conveen Continence Guard) and tested its efficacy in a short-term study in women with the symptom of stress incontinence [38] (Figure 4.15). The guard is a vaginal device made of soft, smooth and highly hydrophilic polyurethane foam. It is arch-shaped and available in 3 sizes. The product is intended to support the bladder neck partly because it is elastic and partly because of the pressure maintained by the two wings. A special applicator ensures correct placement in the vagina and a string attached to the device facilitates removal after use. To prevent the absorption of moisture from the vaginal mucosa, the device is first saturated with water before use. It then becomes soft and enlarges by 30%. A daily change to a fresh device is recommended to minimise the risk of infection. The approved maximum duration of wear is 16 hours per 24-hour period. It may be worn during menstruation but should be changed every 4 – 6 hours [39].

Of the three sizes, the women were instructed to use the largest size that gave minimum discomfort. The device was used in the waking hours only. Table 4.5 shows the results of uroflometry and residual urine with and without the device in place.

Urodynamic variables with & without use of the CCG device

Variables	Without device	With device	Level of significance
Peak Flow (mls/s)	30.6 (14.7 - 60.6)	29.2 (11.6 – 63)	NS
Voided Vol (ml)	359 (132 – 983)	263 (147 – 713)	NS
Residual urine(ml)	20 (0 – 60)	10 (0 – 100)	NS

Table 4.5 Peak flow rate, voided volume and post void residual without and with the vaginal CCG device in place (n = 22). Values are median (range). {Thyssen and Lose (1996)}. NS -= Not significant.

Of the 22 women who completed the study, 9 were subjectively cured and 10 improved while 3 experienced unchanged incontinence. All were said to have decreased leakage on the basis of the 24-hour pad tests with the device in place ($p < 0.005$). The average number of pads used was reduced from 3.2 to 1.4 per day ($p < 0.001$). Eight women had < 8g/24hr leakage. The median and range of values of the PWT gains with and without the device were not reported in the study.
It is interesting to note that the studies reviewed in this thesis suggest those PWT gains of greater than 7-8 g / 24 hrs are abnormal and associated with incontinence. Thus, the data suggest an objective cure in 8(36.4%) women. If analysed on an intention to treat basis this would be 30.7%.

Subjective complaints were few and no vaginal or urinary infections were found. Nineteen of the 22 women wished to continue device use.

Thyssen et al (1998) have assessed the Conveen continence Guard in women with the symptoms of stress incontinence in a more recent study [40]. Of 55 women recruited, 41 (74.5%) completed the study. Before and after 3 months use of the device, the women were assessed by a 48 hour home pad test, a 2 day urinary diary, urine culture and a generic QoL questionnaire (SF 36) and an incontinence specific instrument (Incontinence Impact Questionnaire IIQ). Fourteen women withdrew

because of discomfort when using the device. Subjective cure was achieved in 11(27%) women and improvement in 27(66%), while 3(7%) reported unchanged incontinence. The 48 hour pad test leakage decreased significantly and in 72.5% of the women the leakage decreased by more than 50%. The exact figures for the median and range of PWT gains with the device in situ were not given so it is difficult to interpret whether these changes were also clinically significant. If analysed on an ITT basis 20% were subjectively cured and 49% improved. The number of pads used and the number of leakage episodes on the urinary diary also reduced significantly. The quality of life measured by the IIQ was significantly improved in all the 4 subscales and in the total score. The SF-36 general health questionnaire showed no significant changes. Thirty-two (78%) women completing the study wished to continue device use. Twenty-four women became more physically active during the study period. 14 women who completed the study experienced discomfort.

Hahn and Milsom (1996) also evaluated the clinical efficacy of the Conveen Continence Guard in women with stress incontinence in a multicentre trial [41] (Tables 4.6 & 4.7). They included 90 women with the symptom of stress incontinence, aged 20-65 years, using absorbent pads on a daily basis. Women with a history of urge incontinence, vaginal irritation or discomfort were excluded. They did not comment on whether stress incontinence was the sole symptom or if women with frequency or urgency were excluded from the trial.

Objective tests of urinary leakage were based on a 24hour home provocative perineal pad-weighing test (with physiological bladder filling) before commencing treatment and again during the last week of the trial. The women drank sufficient water to feel the desire to void, so the volume of fluid in the bladder in each case was unknown. Only women with urinary leakage 1g or greater were included in the test. The patients subjective assessment of control of leakage was evaluated using a questionnaire [42]. No validated disease specific instrument was used.

After receiving instructions on how to use the device, women were given a test pack of 3 available sizes and recommended to use the size which gave the best improvement and comfort. The device was kept in the vagina all day but removed overnight for a period of 4 weeks. 90 women (mean age 47.5 years, range 31-65) completed the study. 85 women successfully performed and completed the 24-hour pad-weighing test. Objective results were quoted based on the number completing the trial and not on any intention to treat basis.

Conveen Continence Guard					
	Before treatment		**During Treatment**		**Significance level**
	Mean(SEM)	Range	Mean(SEM)	Range	
Leakage(g)	41.6(7.6)	2-530	13.9 (3.2)	0-187	**p<0.001**
Pads/day	2.5 (0.2)	1-12	1.6 (0.2)	1-7	**p<0.001**

Table 4.6 Results of the 24 hour pad test performed before treatment and at the end of the treatment with the CCG device (n = 85). {Hahn and Milsom (1996)}

Conveen Continence Guard	
Degree of protection	**% change**
Completely Dry	46%
Smaller leakage	29%
Same leakage	17%
Greater leakage	8%

Table4.7 Degree of protection conferred as assessed by changes during pad test with the CCG device in situ (n = 85). {Hahn and Milsom (1996)}

Seventy four per cent of women had a subjective improvement in the degree of leakage or episodes of leakage; 76% also noted a positive effect on the frequency of episodes of leakage. Thirty three per cent of the women were not aware of the device during wear and 34% felt it only slightly; 8% thought the device unpleasant. The device was considered to be satisfactory in 72% of the patients. The subjective evaluation of the device is shown in table 4.8.

Conveen Continence Guard	
Subjective measures	**Mean (SD)**
Inserting device	4.0 (1.8)
Local discomfort	3.9(1.0)
Voiding problems	4.6(1.9)
Defecation problems	3.7(2.4)
Function of the appliance	4.1(2.8)
Removing the device	4.2(1.3)
Overall assessment	3.9(1.1)

Table 4.8 Subjective assessment of the CCG device according to a bothersome scale of 1 to 5; (1 = major problems, 5 = no problems), performed by 90 women. {Hahn and Milsom (1996)}. SD = Standard deviation.

Many of the women (62%) reported some local discomfort during the test, including soreness, irritation, itching and vaginal discharge. However, 72% of these wished to continue device use. Sixty per cent of all women expressed a wish to continue with the same form of treatment after completion of the study, while 19% did not want to

continue and 21% had no opinion. Age did not influence the efficacy or comfort of the device. The authors agreed that a 24-hour pad test was not the best way to assess leakage and that a short reproducible provocative pad test with a standardised bladder volume would be more suitable.

The CCG has also been evaluated in the treatment of urge incontinence in women [43]. Of 24 women with urge incontinence and detrusor instability, two were subjectively continent and 15 reported improvement while 7 were unchanged when using the device. Overall, there was a significant reduction ($p = 0.005$) in the 24 hour pad test and the number of pads used was also significantly decreased ($p = 0.04$). The number of voids and the maximum voided volumes recorded in the urinary diary were unchanged however. It is not reported in the study if the women also had a degree of sphincter incompetence as well as DI.

The effect of the device in improving sphincter incompetence may explain the reduction in episodes of incontinence with urgency. It is known that women with DI are more likely to have urge incontinence in addition to symptoms of urgency if they have a weak sphincter mechanism.

The changes to the bacterial flora in the vagina of 14 women after re-using the Conveen Continence Guard have been recently investigated [44]. The results of 98 guard cycles showed 50% more qualitative bacterial growth in the cervix, but no major quantitative increase of bacteria. Only one patient developed vaginal colonisation by Staph Aureus. No symptoms of toxic shock syndrome were experienced. Overall, re-use of the device caused changes in the vaginal flora but did not increase the infection rate. However, if reused the device was thought to be less effective in controlling stress incontinence.

INTROL BLADDER NECK SUPPORT PROSTHESIS

Introl bladder neck support prosthesis (BNSP) is a flexible device made from medical grade silicone material marketed by Johnson and Johnson Medical PTY Ltd (Figure 4.17 & 4.18). When placed in the vagina, the ridges elevate the urethrovesical junction returning it to a more normal position. This is thought to improve urodynamic parameters in a manner similar to a retropubic urethropexy procedure.

The gutter formed by the ridges ensures the urethra is not compressed by the prosthesis. Unlike vaginal pessaries, the device is loosely fitting and is intended to function under dynamic conditions.

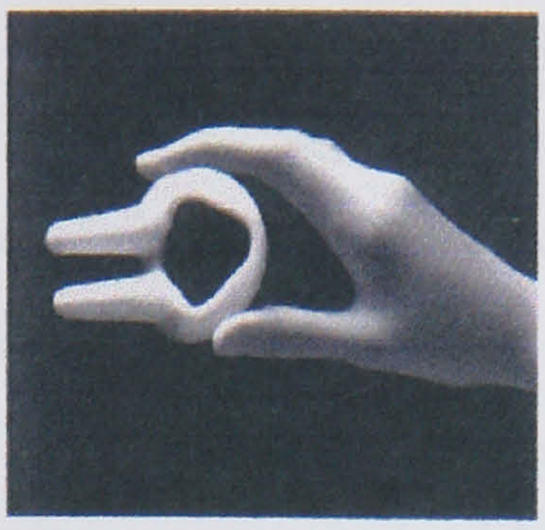


Figure 4.17 Introl Bladder Neck Support Prosthesis.

The use of the Introl Bladder Neck Support Prosthesis was first reported in 1988, for the treatment of GSI and since that time several authors have studied its short-term efficacy [45]. The BNSP received FDA approval for marketing in May 1995 based on the clinical data obtained in the study by Davila and Osterman (1994) [45]. Success rates of 83% - 91% have been reported for usage periods up to 4 weeks in these studies.

Contraindications to the use of this device include:

- Vaginal infections or lacerations
- Pregnancy
- Recent vaginal surgery
- Premalignant changes present in the lower genital tract or frank malignancy.

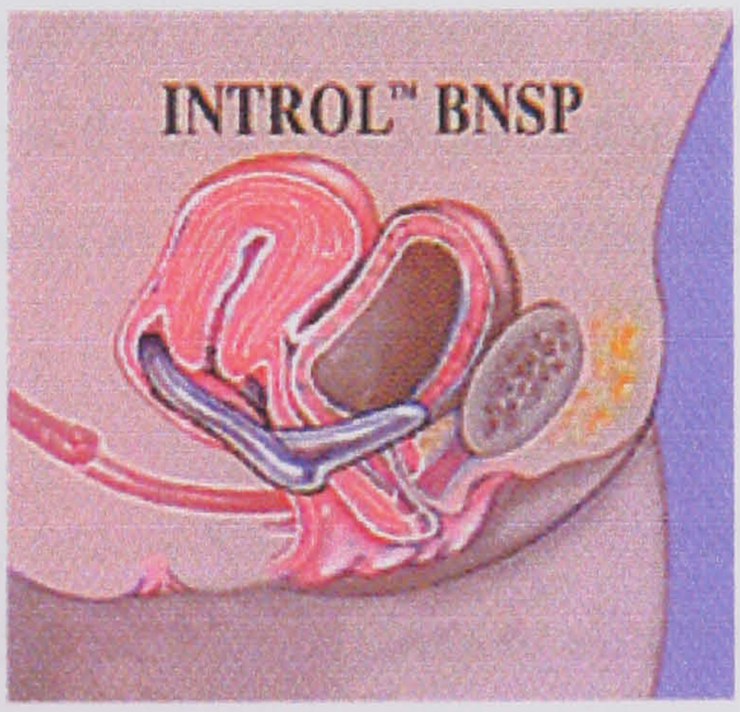


Figure 4.18 Introl Bladder Neck Support Prosthesis in place in the vagina.

Foote et al (1996) carried out a longer-term study of 12 months to assess the use of the BNSP in women with GSI [46]. Evaluation was begun after the women had been

wearing the device successfully for 4 weeks. They were assessed at 3 monthly intervals and at each visit the urine was cultured, clinical examination performed as well as a 1-hour pad weight test. Quality of life questionnaires were completed at the beginning and at the end of the trial, but these were not validated urinary symptom specific questionnaires. Of the 26 women who were wearing the device at week 4, 15 (58%) continued to wear the device for 1 year. Success was defined as either completely dry or >50% reduction in urinary leakage (on both pad test and frequency volume chart). Subjectively, 87.5% of women gave the device a >85% rating for comfort and success. The objective success rate at 12 months was 87.5%. Table4.9 illustrates the change in PWT, leakage episodes on the diary and adverse QoL scores rated out of 10.

Introl bladder neck support prosthesis			
	Baseline	**12 months**	**Significance level**
Mean PWT gains(g)	57	9	**p<0.05**
Leak episodes per day	4.0	0.4	**p<0.003**
Adverse QoL/10	8.1	1.5	**p<0.001**

Table 4.9 Results at Baseline and 12 months of BNSP usage showing change in PWT, leakage episodes on the urinary diary and adverse quality of life scores rated out of 10. (n = 15). {Foote et al (1996)}.

The UTI rate was 15.4% (4 women). Increased vaginal discharge was reported in 54% (14) of women. Superficial vaginal abrasions and polyps were also reported, related to the pressure areas of the ring in the posterior fornix. What is interesting is that 50% of the withdrawals were due to a residual effect, with continuing reduction in urinary leakage after the device was removed. This was not seen in the previous short-term studies and the authors proposed that it could be due to connective tissue remoulding over time around the paraurethral prongs, creating additional bladder neck support.

The BNSP was also assessed by Kondo et al (1997) with respect to safety and efficacy in women with the symptom of stress or mixed incontinence [47]. Outcome measures included an assessment of symptoms, a urinary diary for one week, 60 minute PWT and uroflometry at baseline and at the end of the study (12 weeks). Ninety-three women were recruited but 67 completed the trial. Table 4.10 shows the reasons for dropout.

Introl bladder neck support prosthesis	
Reasons for dropout	**No. of subjects**
Poor manual dexterity	11
Strong apprehension	3
Vaginal bleeding	2
Vaginitis	2
Irritative urinary symptoms	2
Urinary frequency	1
Lost to follow-up	3
Tight introitus	2
Total	26 (28%)

Table 4.10 Reasons for dropout (n = 26) in women using the Introl device. {Kondo et al (1997)}

There was no evidence of urinary obstruction on uroflometry with the device in place. Urine loss decreased from a mean PWT gain of 20.6g to 4.8g ($p<0.001$). Twenty-two (29%) women reported complete continence and 39(51%) had decreased severity of incontinence by more than 50%. Minor adverse events occurred in 26% of the patients. Cystitis occurred in 2 of the patients. There was also a statistically significant improvement in the subjective impression of the frequency of incontinence episodes, bothersome scores related to incontinence, urgency and the amount of urine lost with incontinence.

On a practical note the prosthesis is available in 25 different ring sizes and 3 different prong heights. Hence it is difficult and complicated to get the fit right to achieve optimal results. This is thought to be made more so in the presence of uterovaginal prolapse.

Women who were not satisfied had the following considerations

- Younger (reproductive age)
- Planning further childbearing
- Leaked with specific activities
- Urogenital atrophy
- Scarred vaginal canal from previous surgery

URETHRAL PLUG

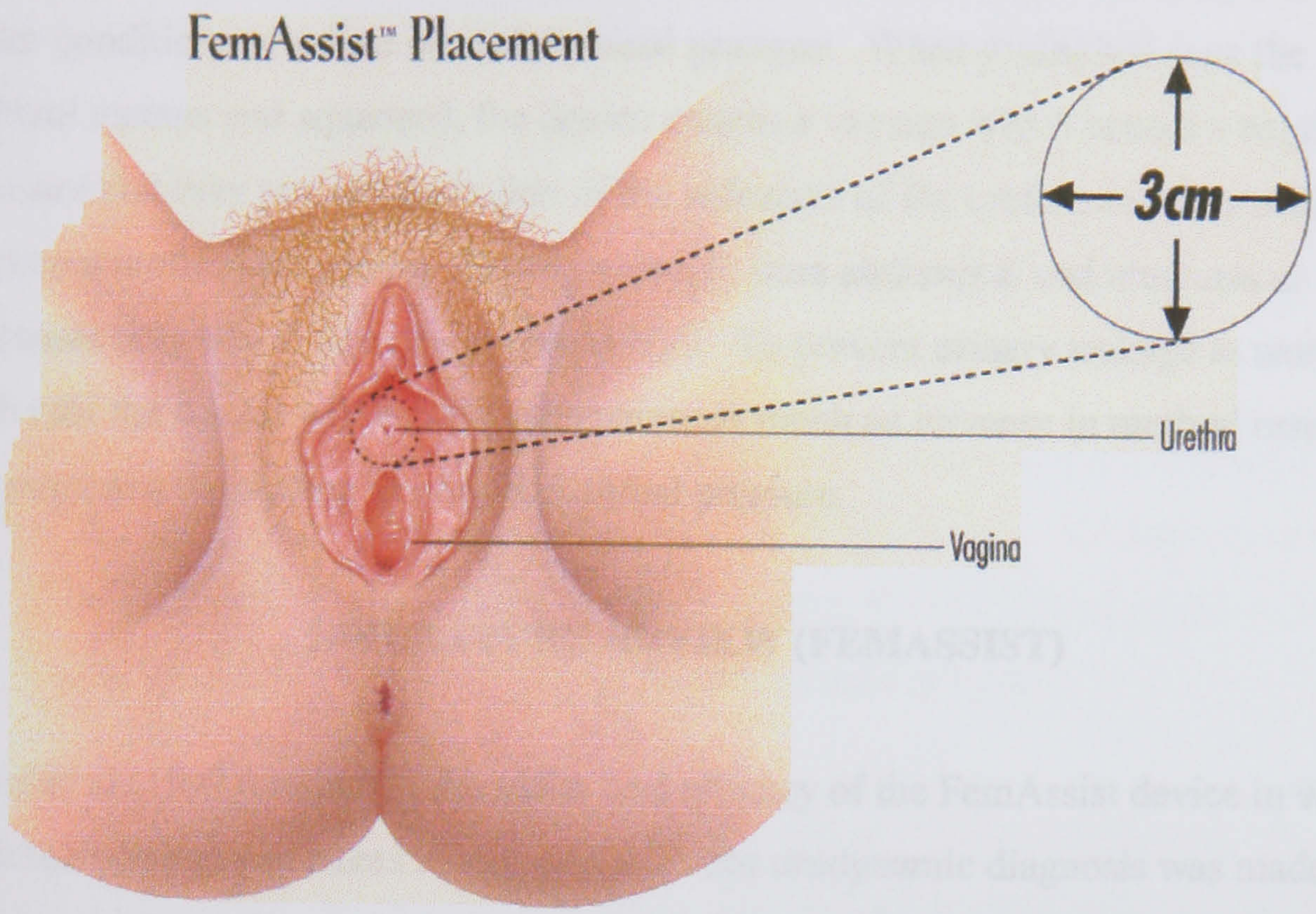
In 1990, Nielsen et al introduced the urethral plug (Pharmaplast, Copenhagen, Denmark) as a new form of treatment for women with GSI [48].

They developed the urethral plug which was to ultimately become the forerunner to the Reliance device. Twenty-two women completed that study of a device with two spheres, one sat in the urethra and the other distally at the bladder neck. The spheres were already inflated and were 7mm in diameter. The subjective and objective improvement rates were in the region of 73% in women with GSI. There were problems however with device insertion and study design. In this study, there was a high rate of patient compliance and a large subjective and objective success rate. However, the treatment was not without problems. The plug was very soft and insertion was often difficult. Also, the plug was individually fashioned according to the urethral closure pressure profile results. This process was cumbersome and expensive. To avoid these problems, the urethral plug II was developed. The plug is composed of non-toxic thermoplastic elastomer material and comprises an oval meatal plate, a soft stalk and 1 or 2 spheres 7mm in diameter along the stalk. Inside the stalk there is a semi-rigid removable guidepin. On the 2-sphere plug the distal and proximal spheres are located 1.8 and 3 cm respectively from the meatal plate. On the 1-sphere plug the sphere is located 2.0 cm from the meatal plate. These distances were based on the median distances from the external urethral orifice to the maximal urethral closure pressure profile results reported in the first study.

Nielsen et al (1993) assessed the efficacy of this improved design of urethral plug in women with GSI [49]. The study consisted of 3 trial periods. Patients were allocated randomly to either the 2-sphere or the 1-sphere plug during period 1 (2 weeks). In period 2 (2 weeks) they used the other device. They then chose what they considered to be the better plug and continued to use it for a further 2 months (period 3). Assessment at each stage was by means of symptom analysis, urine culture, uroflometry and the pad-weighing test at 50% bladder capacity with the plug in the urethra. Forty women were assessed, 20 to each of the two devices in period 1, but only 18 (45%) completed the trial. Fourteen of the 18 preferred the 2-sphere plug. Subjectively and objectively 17(43%) were continent or only rarely incontinent with the preferred plug. Overall, there was no difficulty with insertion. The plugs were equally effective in women with mild or severe GSI. Six women developed UTIs and 2 of these had the plug migrate into the bladder. Loss of plugs falling out of the urethra during use was a problem. This occurred in cases where the distances from the meatal plate to the distal sphere was less than the measured distance from the external urethral orifice to the maximal urethral pressure on the UPP. If the distal sphere was above the sphincter at the bladder neck than this was not a problem generally.

FEMASSIST

FemAssist Urinary Incontinence Device is a cap-shaped device, composed of silicone rubber (Figure 4.20). It is designed to be placed directly over the urethra where it will be held in place by its own mild vacuum action. When using the FemAssist Urinary Incontinence Device, a small amount of lubricating gel is placed on the surface which comes in contact with the body. This helps maintain the vacuum seal and protects against accidental urine loss. The device stays in place for as long as is comfortable. When the woman wishes to void, she removes the device by pulling the base away from the urethra. The device should then be cleaned with soap and warm water and replaced in the urethra. The device should be disposed of at the first signs of wear or after 7 days.



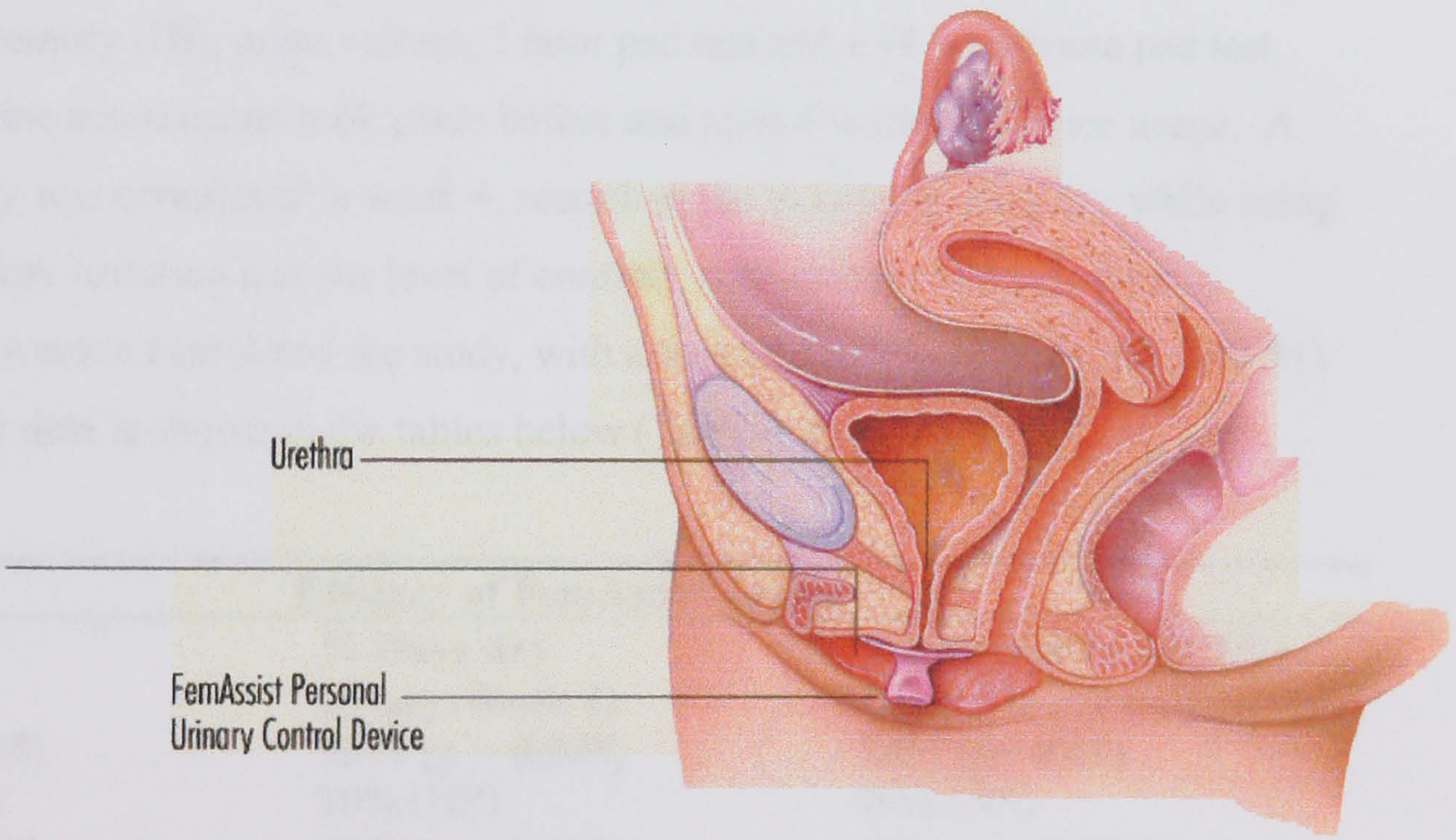


Figure 4.20 Placement of the FemAssist device

Mechanism of Action

It is uncertain how the FemAssist device works in practice to prevent urinary leakage under conditions of raised intra abdominal pressure. When positioned over the urethral meatus and squeezed, the device creates a vacuum which causes a negative pressure that may permit coaptation of the sidewalls of the urethra and presumably increases urethral resistance. During a cough, intra abdominal and intravesical pressures may rise to as high as 150cm H_2O. To prevent urinary leakage in women with GSI the device would have to generate as much an increase in urethral resistance to counteract these rises in intra abdominal pressure.

LITERATURE REVIEW (FEMASSIST)

Versi et al (1997) evaluated the safety and efficacy of the FemAssist device in women with the symptom of stress incontinence [50]. No urodynamic diagnosis was made prior to entry to the study. Assessment consisted of a symptom questionnaire, gynaecological examination, visual analogue score (VAS) to document the severity of symptoms, quality of life questionnaire (Incontinence Impact Questionnaire (IIQ) and Distress Inventory (DI), urine culture, 1 hour pad test and a 48 hour home pad test. These baseline assessments took place before and after 4 weeks of device usage. A urinary diary was completed in week 4, recording the number of days dry while using the device, any irritation and the level of comfort, convenience and satisfaction. Ninety-one women completed the study, with a mean age of 54 years (range 29 – 81). The efficacy data is shown in the tables below (Table 4.11 & 4.12)

	Efficacy of FemAssist device	
Symptom	**% Days dry (Diary:Week 4)**	**%Decrease in PWT(g)**
Stress (n = 38)	**73% (p = 0.005)**	**74% (p< 0.02)**
Urge (n = 9)	90% (NS)	99% (NS)
Mixed (n = 44)	**62% (p = 0.001)**	**62% (p = 0.005)**
Total (n = 91)	**69% (p < 0.001)**	**68% (p = 0.001)**

Table 4.11 The percentage (and significance level) of dry days recorded in the urinary diary and the change in the PWT (and significance level) while wearing the FemAssist device analysed according to groups where the predominant symptom was stress, urge or mixed incontinence. {Versi et al (1997)}. NS = not significant.

Efficacy of FemAssist device		
Symptoms	**% improvement in IIQ Scores**	**% Decrease in Distress Inventory scores**
Stress (n = 38)	**55% (p < 0.0001)**	**40% (p < 0.001)**
Urge (n = 9)	67% (NS)	32% (NS)
Mixed (n = 44)	**52% (p < 0.0001)**	**27% (p <0.001)**
Total (n = 91)	**54% (p < 0.0001)**	**32% (p < 0.001)**

Table 4.12 Quality of life improvement (IIQ and DI instruments) with significance levels while wearing the FemAssist device analysed according to groups where the predominant symptom was stress, urge or mixed incontinence. {Versi et al (1997)}
NS = not significant.

Irrespective of the type of symptom of incontinence, the device was effective in reducing incontinence and improving the quality of life scores. VAS scores improved ($p < 0.001$) for incontinence (stress: 6.0 to 3.3; urge: 4.0 to 2.7) and urgency (3.9 to 3). There was no increase in asymptomatic bacteriuria or cystitis.

Rabin (1997) also assessed the safety and efficacy of the FemAssist device in women with GSI or mixed incontinence [51]. Thirty-eight women were recruited to the trial which lasted one month. Subjective assessment included quality of life questionnaires, daily voiding and activity diaries while objective assessment included urine microscopy and culture and clinical examination. All subjects completed the trial and over 50% reported an improvement in their quality of life including comfort, convenience and overall satisfaction. In total for all the women, the device was worn on a total of 886 days; 82% of these were dry days. Similar results were obtained for women regardless of the urodynamic diagnosis. One in five reported vulval irritation or urethral discomfort at some point, but this did not correlate with percentage of dry days. The rate of bacteriuria and cystitis was not reported but it was stated that there was no significant increase in these adverse events over and above the patients baseline experiences.

Prashar et al (1997) also evaluated the changes in quality of life in women using the FemAssist device [52]. The device was offered to women complaining of stress, urge or mixed incontinence, but a urodynamic diagnosis was not made as part of the inclusion criteria. Subjects underwent a pad test, dipstick urinalysis and a cost of continence questionnaire. Quality of life was assessed using the IIQ and DI instruments. Patients were randomised to control (device plus a leaflet on good bladder habit) and treatment

groups (device plus pelvic floor exercises and/or bladder drill). Women were assessed weekly for 6 weeks. Of the 65 women recruited, 19 (29.2%) did not complete the protocol as shown in table 4.13. 26 completed the trial and 20 were ongoing.

FemAssist	
Reasons for dropout	**No. of subjects**
Inability to apply device	6
Extreme anxiety	5
Can not touch genitalia	5
Disliked the device	1
Requested other therapy	1
Lack of time	1

Table 4.13 Reasons for dropout (n = 19) in women using the FemAssist device. {Prashar et al (1997)}

The average age was 64.1 years (range 25 – 87). Of the 26 women who completed the trial, 7 were objectively dry and a further 7 had minimal loss (PWT < 2g). Both groups had similar improvements in PWT and QoL scores as illustrated in table 4.14. Weekly personal cost of incontinence fell from a mean of Aus$3.90 to Aus$1.35. All 26 women found the device comfortable, easy to use and would continue to use it.

FemAssist			
	Efficacy of device		
Outcome measures (mean value)	**Baseline**	**6 weeks**	**Significance level**
PWT(g)	55.7 g	17.8 g	**p<0.01**
QoL score	52.6	37.5	**p < 0.001**

Table 4.14 The changes in mean PWT gains and mean Q of L scores from baseline after 6 weeks of FemAssist device use (n = 26). {Prashar et al (1997)}

Tincello et al (1997) have evaluated the efficacy and acceptability of the FemAssist urinary control device in women with GSI and a pad test result which was representative of their daily loss [53]. A repeat 1-hour perineal pad test was performed with the device positioned on the patient by a member of the nursing staff. After the pad test, all women were given a questionnaire containing three 100mm visual analogue scales (VAS) to measure discomfort, acceptability and embarrassment associated with wearing the device (Table 4.15).

FemAssist			
Efficacy of device			
PWT (g)	**Without Device**	**With FemAssist**	**Significance level**
Median (range)	21 (1 – 94)	4.9 (0 – 65)	**p< 0.01**

Table 4.15 Pad weight tests results with and without the FemAssist device in place (n = 27). [Tincello et al (1997)}.

Seven women (26%) were made "wetter" with the device in place with a median increase in pad weight gain of 7g (0.6 – 24.4g). Twenty women (74%) were made "drier" with the device with a median reduction in pad weight gains of 13g (0.6 – 43.1g). Table 4.16 shows the VASs for each subjective measure of the device.

FemAssist	
Subjective outcome measures	
Subjective measure	**VAS score (median, range)**
Discomfort	35 (4 – 93)
Embarrassment	11 (0 – 75)
Acceptability	65 (13 – 100)

Table 4.16 Visual analogue scores for each subjective measure associated with FemAssist device use. {Tincello et al (1997)}

The scores for discomfort were significantly greater in the patients who were wetter with the device than in the drier group ($p < 0.05$). There was a negative correlation between the acceptability score and the discomfort score ($R = 0.53$, $p < 0.01$). Acceptability was also correlated negatively with embarrassment ($R = 0.39$, $p < 0.05$) and with patient age ($R = -0.30$, not significant); embarrassment was correlated positively with discomfort ($R = 0.47$, $p < 0.05$). Fifteen women (56%) said they would consider using the device as a permanent continence aid, six (22%) would not and six were undecided.

There are some interesting issues posed by Tincello's study of the FemAssist device. They found that the amount of benefit was not predictable. Benefit did not relate to the severity of the initial problem or severity of GSI. There was a variable degree of improvement in those who were made drier. The reason for the wide range of benefit observed with the device (based on the PWTs) is unclear. Several women were actually made worse when using the device which was not anticipated. It is possible that urethral irritation or discomfort may trigger abnormal detrusor activity. It was noted that increased discomfort VASs were recorded among women who were wetter

with the device in place compared with those who benefited. The devices were put in place over the urethra by the investigators for trial tests. It may be that, in practice, patients would be much better at placement. The investigators used the Sutherst method of PWT, which has problems of reproducibility[54]. Acceptability was also variable and discomfort was a major factor determining acceptability.

RELIANCE

The Reliance device is composed of non-toxic, thermoplastic material and comprises an oval meatal plate, a soft stalk and one sphere located at the distal end of the stalk (Figure 4.21). It is intended to act as a temporary barrier inside the urethra, to keep urine from leaking out of the bladder until the woman is ready to go to the lavatory. The device is gently inserted into the urethra. Then a small balloon at the tip of the device is inflated, using a syringe-like applicator, to block the bladder neck opening and prevent the flow of urine. The applicator is then removed, and the device remains comfortably in place as the bladder fills normally. When the woman desires to go to the lavatory, a simple tug on the device's string will deflate the balloon, allowing her to easily remove it. After urinating, she simply inserts a new Reliance.

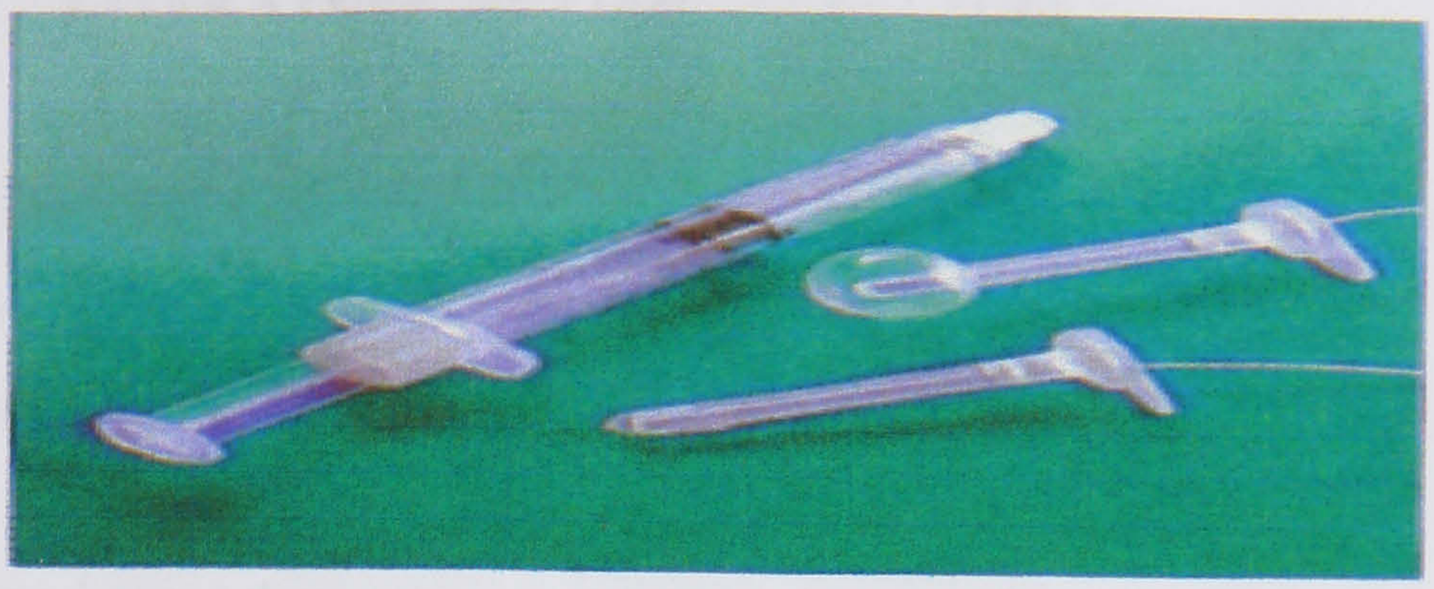


Figure 4.21 Reliance device

LITERATURE REVIEW (RELIANCE)

Staskin et al (1996) have published the largest study to date on any continence device and evaluated the safety and efficacy of the Reliance urethral insert in the management of women with stress or mixed incontinence [55]. They included women aged 18 – 75 years with pure or mixed incontinence (cystometric motor urgency < 20 cm H_2O) [56] who experienced three or more incontinence episodes per week. All patient evaluations (at entry and at 4 months) included clinical examination, urine microscopy and culture, cystoscopy and cystometry. If women were thought to have intrinsic sphincter deficiency, urethral function was assessed by Valsalva leakpoint pressures, urethral pressure profiles or standing video fluoroscopy. Other outcome measures included a standardised PWT, 7 day urinary diary (monthly) and subjective assessment of urinary leakage (1 to 5 scale), ease and comfort of use.

The SF-36 general health quality of life questionnaire was also completed at the start and end of the study. A total of 215 women were enrolled in the study but 80 (37%) withdrew before 4 months. The reasons for withdrawal are illustrated in table 4.17.

Reliance device

Reason for withdrawal

Dropout	**No of Patients (%)**
Discomfort	25 (11.6)
Inability to use device	18 (8.4)
Urgency	6 (2.8)
Recurrent cystitis	6. (2.8)
Lost to follow-up	5 (2.3)
Leakage with device	5 (2.3)
Haematuria or urethral irritation	4 (1.9)
Non-compliance with protocol	3 (1.4)
Other reasons	8 (3.7)

Table 4.17 Reasons for withdrawal before completion of 4 month study (n = 215). {Staskin et al (1996)}

No statistical differences were observed between patients who completed the study and those who did not when demographic characteristics, urologic history or presenting symptoms were examined ($p > 0.05$). Pad test weight data were available on 114 of the 135 patients and the clinical efficacy of the device as assessed by PWT gains at baseline and at 4 months are illustrated in table 4.18.

Efficacy of the Reliance device			
Baseline Period			
Urine loss* without device	Urine loss* with device	Change in Urine loss*	Significance level
42.7 (4.5)	**2.2 (0.6)**	**40.5(4.3)**	**p<0.0001**
4 month Period			
Urine loss without device*	Urine loss with device*	Change in Urine loss*	Significance level
43.3 (4.9)	**3.2 (0.7)**	**40.1 (4.7)**	**p< 0.0001**

Table 4.18 Analysis of improvement in urine loss based on PWT gains at baseline and at the end of the study. * Mean PWT gain in grams (standard error of mean). {Staskin et al (1996)}

Device use resulted in a statistically significant improvement in urine loss irrespective of the type of GSI (anatomic or intrinsic sphincter deficiency) or the presence of previous continence surgery. The authors state the data reveal that 80% of the women were completely dry and 95% achieved >80% improvement in urine loss. There was also an improvement in incontinence symptoms in 89% based on daily urinary diaries. What is unclear is whether or not these data were analysed on an intention to treat basis (n = 215) or were they analysed based on the core group with available PWT data (n = 114) who attained 4 months of device use. Based on an ITT, the data would correspond to 50.2% (108) clinical effectiveness and 47% (101) improvement on urinary diary. Therefore their conclusions that the device, in this study, compared favourably with other currently available non-surgical therapies is probably inaccurate.

Adverse events during the study were transient and required only minor medical intervention. The rate of UTI is shown in the table 4.19.

Safety of the Reliance device	
Urinary tract infections	
Positive culture (not treated) (>/= 10^4 cfu/ml)	52 (39%)
Positive culture (treated)	42 (31%)
Asymptomatic	15 (11%)
Symptomatic	27 (20%)

Table 4.19 Urinary tract infections observed during the 4 month study (n = 135). {Staskin et al (1996)}

All but a few cystoscopic examinations indicated normal urethra and bladder mucosa. Urodynamics showed no compromise in bladder function at the end of the trial. What was observed which gave rise to some concern was a trend towards an increased urine loss without device use from baseline to 4 months. This trend was statistically significant in the case of women with intrinsic sphincter deficiency with prior surgery {n = 11, mean PWT gain 68.6g at baseline, 92.3g at 4 months, $p<0.01$}. The authors felt that uninhibited bladder contractions (not noted on cystometry) may have contributed to the degree of urine loss observed in this group. They did not comment on the possibility that the insert itself may cause deterioration in the already compromised sphincter mechanism due to repeated device insertions. By the end of the study, patients' perception of acceptability, degree of incontinence, symptom improvement, ease of learning, comfort and time to habituation also showed improvements.

There are problems in conducting a multicentre trial however. This was a multicentre (7) study, and exactly what measures were taken to ensure that all women were studied in a consistent manner (i.e.: urodynamic standards of practice and equipment as well as computer software and calibration) was not made clear.

The Reliance device was also evaluated in a French multicentre trial [57]. One hundred women with GSI or mixed incontinence were recruited to use the device over 3 months. Women underwent clinical assessment, urodynamics, PWTs and completion of a one-week diary. The mean age was 56.4 years and 32% had previous

continence surgery. Sixty one per cent had pure GSI. The dropout rate was 36%, due to discomfort, difficulty with insertion or persistent leakage while using the device. Of the 64 women completing the 3-month study, the PWT showed an improvement from a baseline mean of 36g without the device to 10g with the device in situ. In 71% of cases, the PWT was negligible with the device in situ. Total clinical experience represented 293 patient months and the use of 26,300 devices. Fourteen UTIs, 14 haematuria and 2 intra-vesical device migrations were reported. More than half those completing the study wished to continue device use.

Miller and Barendam (1996) have published their 12-month experience of the effectiveness and safety of the Reliance Urinary Control Insert [58]. Sixty-three women with pure GSI or mild mixed incontinence who experienced three or more incontinence episodes per week were recruited. Women with urge incontinence and involuntary detrusor contractions >20cm H_2O were excluded. The mean age of the subjects was 55 years [± 1.5 (SEM)] with a mean duration of incontinence of 12.5 years [± 1.3 (SEM)] and a parity of 2.4 [± 0.17 (SEM)]. Twenty-eight (44%) were on hormone replacement therapy and one third had undergone previous continence surgery. Urodynamics showed that 62 (98%) had pure GSI and one had mixed incontinence. Monthly evaluations included a vaginal examination and urine microscopy and culture. Cystoscopy and cystometry were repeated at 4 and 12 months. Effectiveness was analysed by a 1-hour pad weight test and a urinary diary. The PWT was conducted at 4 and 12 months and the diaries were kept for 7 days at baseline and monthly intervals. Objective assessments of safety were made through routine urinalysis, urine cultures and cystoscopy to assess mucosal changes of the urethra and bladder, as well as any adverse events reported. Subjects used an average of 3 inserts daily, each worn for 2-3 hours.

Fifty-six women completed the 12-month PWT analysis (table 4.20). At the study outset, 46 women (82%) were completely dry and 9 (16%) were significantly improved. At 12 months 44 (79%) remained completely dry and 9 significantly improved. Three women exhibited <50% improvement in PWT at 12 months but had significant improvement in incontinence episodes on their urinary diaries.

Efficacy of the Reliance device based on reduction in mean PWT gains			
Baseline Period			
Urine loss Without device*	Urine loss with device*	Change in Urine loss*	Significance Level
46.4 (7.2)	**2.4 (0.9)**	**44.0 (6.8)**	**p< 0.0001**
12 month follow-up			
Urine loss Without device*	Urine loss with device*	Change in Urine loss*	Significance Level
41.5(6.2)	**5.3 (2.3)**	**36.2 (5.7)**	**p< 0.001**

Table 4.20 Reduction in urine loss with and without the Reliance device from the baseline period to 12 months (n = 56) based on PWT analysis. {Miller and Barendam 1996}. * Expressed as mean PWT gains in grams (SEM).

Women who had previous failed continence surgery had a significantly higher mean PWT gain at baseline, but the device produced a similar reduction in leakage. Table 4.21 illustrates the degree of protection achieved with device use comparing baseline diary data with that of device use at 1 month and 12 months.

Subjective degree of protection afforded by the Reliance device				
	Before Use	**1 month**	**12 months**	**Significance level**
Activity	**Completely dry**	**Completely dry / sig. Improved**	**Completely dry / sig. Improved**	
Sitting	34	87	96	**0.001**
Standing	27	84	88	**0.003**
Walking	14	69	84	**0.001**
Lifting	10	88	90	**0.001**
Low impact exercise	20	100	92	**0.005**
High impact exercise	0	100	89	**0.005**
Coughing	3	73	84	**0.002**

Table 4.21 Percentage of women reporting dryness or significant improvement during Reliance use. Completely dry = rating of </= 1.09 on a scale of 1-5 (1 = no leakage, 5 = large leakage). Significant improvement = >50% reduction in rating urine loss during insert use compared with before use. {Miller and Barendam 1996}.

Patients rated the ease of insertion and comfort of use on a scale of 1 – 5 {(easy – difficult) and (comfortable – very uncomfortable)}. The results are shown in table 4.22.

Subjective outcome measures of the Reliance device			
Measure	**1 month**	**12 months**	**Significance level**
Ease of insertion	1.74	1.20	**p< 0.0001**
Comfort of use	2.49	1.52	**p< 0.0001**

Table 4.22 Ease of insertion and comfort of use at one and twelve months use of the Reliance device. The numbers refer to the mean score {scale of 1 – 5 (1= easy, 5= difficult) and (1= comfortable – 5= very uncomfortable)} at the period of assessment. {Miller and Barendam 1996}

After one week of use, 22 (35%) women experienced a foreign body sensation and this declined to 4 (7%) women at one year. The adverse events experienced during the trial and the cystoscopic findings are shown in table 4.23.

Adverse events experienced with the Reliance device	
Adverse event	**Number of subjects**
Microscopic haematuria	53 (84%)
Gross haematuria	15 (24%)
Cystitis	19 (30%)
Asymptomatic bacteriuria	11 (18%)
Cystoscopic Findings	
Mild mucosal inflammation	1
Mild mucosal erythema of bladder neck	1
Trigone erythema	1
Mild inflammation of dome	2

Table 4.23 Adverse events noted over 12 months of Reliance device use. {Miller and Barendam 1996}.

There was no significant change in urine loss without the device from baseline and at 12 months (46.4 ± 7.2 g at baseline; 41.5 ± 7.1g at 12 months, mean and standard deviation). The success rates of 80% (completely dry on PWT) to 95% (completely dry or significant improvement on diaries) obtained in this study compare favourably with those observed with surgical interventions [59]. The PWT data also correlated well with the urinary diaries kept by the subjects. There were good results achieved with most provocative activities. Efficacy was maintained consistently at 1 – 12 months and previous surgery did not interfere with the results. There was also no deterioration in the PWT results without the device at the end of trial as a result of using the device: - inferring no deterioration in the continence mechanism.

The rate of 30% symptomatic cystitis in 12 months was well within the range observed for the incontinent female population, where recent studies have estimated rates of 28% - 35% for the ageing woman [60].

CONCLUSION

Product development and testing is an arduous area of research; yet for patient safety it is one in which nurses and clinicians should become more actively involved. The development of continence aids may provide women with a treatment and cost alternative from protective clothing, pads and diapers as well as enhance their quality of life. In addition, nursing time needed for incontinence care may also decrease.

References

[1] Association for Continence Advice. Directions of Continence and Toileting aids. London ACA, 1992

[2] Cottenden A. Aids and Appliances. In Roe B, ed. Clinical nursing practice : promotion and management of Continence London : Prentice Hall, 1991

[3] Fourcroy J. Urogynaecology Update: Incontinence. Hosp. Pract 1998;May 15:63-81

[4] Edwards L. Mechanical and other devices. In Caldwell K (ed). Urinary Incontinence. London Sector Publishing Ltd. 1975:115-27.

[5] Lowhtian P. Portable urinals for women. Nursing times 1975;71:1739-41

[6] Terman LA (1964). Intravaginal urinal (Patent No. 3,116,734). Washington DC : United States Patent Office.

[7] Fielding P, Wells TJ. (1975). Urinary collecting device: A clinical trial among female geriatric patients. Nursing Times, 71, 136-137.

[8] Hollister Female Urinary Pouch (1986). Clinical Report, Project number 232. Libertyville, IL : Hollister, Incorporated.

[9] Breece LK. (1965) Urinary device (Patent No. 3, 194,238). Washington DC: United States Patent Office.

[10] FEMEX: Female external urinary catheter description and instructions (1982). Round Rock, TX: Medoc Corporation.

[11] Michaud RB (1981). Urine collection device (Patent No. 4,246901). Washington DC: United States Patent Office.

[12] Blackmon GD. (1984) Female external catheter (Patent No. 4, 484,917). Washington DC: United States Patent Office.

[13] Williams AJ (1949). Device for control of urination (Patent No. 2,438,079). Washington DC : United States Patent Office.

[14] Johnson D, O'Reilly J, Warren J. Clinical evaluation of an external urine collection device for non-ambulatory incontinent women. J Urol 1989;141:535-37

[15] Keane FX (1971). Mechanical aids to nursing paraplegics. Nursing Times, 69,1606-1607.

[16] Crowley IP, Cardozo L, Lawrence LC (1971). Female incontinence: a new approach. British Journal of Urology, 43, 492-498.

[17] Hall KF & Beecher WH (1985). External female urinary appliance (Patent No. 4, 496355). Washington DC: United States Patent Office.

[18] Li LR (1977). Urinal device (patent No. 4,023,216). Washington DC: United States Patent Office.

[19] Edwards L and Malvern J: Long-term follow-up results with the pubo-vaginal spring device in incontinence or urine in women: comparison with electronic methods of control. Brit J Urol.,45:1031973

[20] Lindan R. The design and preliminary trials of an external appliance for women with neurogenic bladder dysfunction. Proc. Veterans Administration Spinal Cord Injury Conference, 18:101,1971

[21] Department of Health, Local Authority contracts for residential and nursing home care: NHS related aspects. HSG (92)50. London DOH, 1992

[22] Department of Health Continence Services and the supply of incontinence aids. EL (91)28. London : DOH, 1991

[23] Peate I. Patient management following suprapubic catheterisation. Br J Nurs, 1997. 6(10): 555-62.

[24] Nygaard I, Zinmeister A. Treatment of exercise incontinence with a vaginal pessary: A preliminary study. Int Urogynecol J. 1993;4:133-137

[25] Fihn S, Johnson C, Pinkstaff C, Stamm W. Diaphragm use and urinary tract infections: analysis of urodynamic and microbiological factors. J Urol 1986;136:853-6

[26] Suarez G, Baum N, Jacobs. Use of standard contraceptive diaphragm in management of stress urinary incontinence. Urology 1991;28:119-22.

[27] Realini J, Walters M. Vaginal diaphragm rings in the treatment of stress urinary incontinence. J Am Board Fam Pract 1990;3:99-103.

[28] Nygaard I. Prevention of incontinence with mechanical devices. J. Reprod Med 1995;40:89-94

[29] Bhatia N, Bergman A. Pessary test in women with urinary incontinence. Obstet Gynecol 1985;65:220

[30] Bhatia N, Bergman A, Gunning J. Urodynamic effects of a vaginal pessary in women with stress urinary incontinence. Am J Obstet Gynecol 1983;147:876-884

[31] Leong F, Brubaker L. Use of the incontinence ring in stress incontinence. Int. Urogynecol J 7(5):295

[32] Monga A, Beyar M, Nativ O, Stanton S. A new intra urethral sphincter prosthesis for retention: preliminary clinical results. Neurourol Urodynam 1996;15(4):406-407.

[33] Nativ O, Moskowitz B, Issaq E ,et al. ASAIO Journal 1997;43:197-203

[34] North B. A disposable adhesive patch for stress urinary incontinence. Fam Med 1998;30(4):258-264.

[35] Bellin P, Smith J, Pok W et al. Results of a multicentre trial of the CapSure [Re/Stor] continence shield on women with stress urinary incontinence. Urology 1998;51:697-706.

[36] Wagner T, Patrick D, Bavendam T, Martin M, Buesching D. Quality of life of persons with urinary incontinence: development of a new measure. Urology 1996;47:67-72.

[37] Eckford S, Jackson S, Lewis P, Abrams P. The continence control pad – a new external urethral occlusive device in the management of stress incontinence. BR J Urol 1996;77:538-40.

[38] Thyssen H, Lose G. New disposable vaginal device (Continence Guard) in the treatment of female stress incontinence. Design, efficacy and short term safety. Acta Obstet Gynecol Scand. 1996;75:170-173.

[39] Thyssen H, Lose G. New disposable vaginal device in the treatment of female stress incontinence. Design, efficacy and short term safety. Acta Obstet Gynecol Scand 1996;75:170-3

[40] Thyssen H, Sander P, Lose G, Andersen J. Impact of Quality of Life of a vaginal device in women with urinary stress incontinence. Neurourol Urodynam 1998;17(4):349 – 350.

[41] Hahn I, Milsom I. Treatment of female stress urinary incontinence with a new anatomically shaped vaginal device (Conveen Continence Guard). Br J Urol 1996;77:711-15

[42] Victor A, Larsson G, Asbrink A. A simple patient administered test for objective quantification of the symptom of urinary incontinence. Scand J Urol Nephrol 1987;21:277-9.

[43] Thyssen H, Sander P, Lose G. Vaginal device (Continence Guard) in the treatment of urge incontinence in women. Neurourol (Urodynam 1997;16(5):484-486.

[44] Van Zon-Rabclink I, Laven J, Vlengels M. The Conveen Continence guard: Re-usable? Int Urogynecol J. 1997;8(1):522.

[45]Davila G, Osterman K. The Bladder neck support prosthesis: A non-surgical approach to stress incontinence in adult women. Am J Obstet Gynecol 1994;171:206-11.

[46] Foote A, Moore K, King J. A prospective study of the long-term use of the bladder neck support prosthesis. Neurourol Urodynam 1996;15(4):404-406.

[47] Kondo A, Yokoyama E, Koshiba K et al. Bladder neck support prosthesis: a non-operative treatment for stress or mixed urinary incontinence. J Urol 1997;157:824-27.

[48] Nielsen K, Kromann-Andersen B, Jacobsen H et al. The urethral plug: a new treatment modality for genuine stress incontinence in women. J Urol 1990;144:1199-1202.

[49] Nielsen K, Walter S, Maegaard E, Kromman-Andersen B. The urethral plug II: An alternative treatment in women with genuine urinary stress incontinence. Br J Urol 1993;72:428-432.

[50] Versi E, Griffits D, Giovannini P. Improvement in Quality of Life and urinary incontinence using the FemAssist device. Int Urogynaeco J 1997;8(1):566.

[51] Rabin J. The FemAssist: a new device for the treatment of female urinary incontinence. Int Urogynecol J 1997;8(1):S1.

[52] Prashar S, Moore K, Bryant C, Powell C. The urethral occlusive device for the treatment of urinary incontinence: changes in quality of life.

[53] Tincello D, Bolderson J, Richmond D. Preliminary experience with a urinary control device in the management of women with genuine stress incontinence. Br J Urol 1997;80:752-56.

[54] Sutherst J, Brown M, Richmond D. Analysis of the pattern of urine loss in women with incontinence as measured by weighing perineal pads. Br J Urol 1986;58:273-8

[55] Staskin D, Barendam T, Miller J et al. Effectiveness of a urinary control insert in the management of stress urinary incontinence: early results of a multicentre study. Urology 1996;47(5):629-636.

[56] Sand P, Brubaker L, Novak T. Simple standing incremental cystometry as a screening method for detrusor instability. Obstet Gynecol 1991;77:453-57

[57] Pigne A, Bitker M, Cotelle-Bernede O et al. Reliance urinary control insert – result of a French multicentre study. Int Urogynecol J 1997;8(1):8128.

[58] Miller J, Barendam T. Treatment with the Reliance Urinary Control insert: one-year experience. J Endourol 1996; 10(3):287-92.

[59] Jarvis G. Surgery for genuine stress incontinence. Br J Obstet Gynecol, 1994. 101(5): 371-4.

[60] Resnick N, Yalla S, Laurino E. The pathophysiology of urinary incontinence among institutionalised elderly persons. N Engl J Med 1989; 320:1

CHAPTER FIVE

URODYNAMIC ASSESSMENT

SYMPTOMS

Patients usually consult their doctor seeking alleviation of symptoms and treatment of problems. Women are unlikely to introduce the subject of urinary incontinence unless the symptoms are incapacitating. Failure to discuss these issues prevents women from taking advantage of possible treatment options that have become available [1]. Before any treatment is instituted however, one must determine the nature of the complaint. Diagnosis and clinical evaluation of the problem is the initial and vital element in the management of women with urinary symptoms. The cause and the outcome of the illness are often influenced by the physician's ability to reach an early and correct diagnosis.

The patient's medical history is the most important part of the clinical database [2]. In general medical terms a patient's history probably serves as a basis for 70 – 80% of correct diagnoses [3]. Patients are given sufficient time to discuss their problems and complaints, but we provide direction to the consultation using the KHQ. With direct questioning, additional information is obtained for further clarification of the urinary symptoms. It is important to realise that these symptoms are not experienced similarly or expressed with the same intensity by all women. Patients vary widely in their responses to the same disease process, based on their age, cultural background and constitutional and genetic make-up. Patients may present with common, complex, mixed or atypical urinary symptoms. Symptoms may also be forgotten, suppressed, or exaggerated by patients.

Clues may be so definite that their presence confirms the diagnosis or so sensitive that their absence effectively eliminates certain diagnoses [4]. However, most women with urinary incontinence present with mixed symptoms. Even though GSI is the most common condition, an audit of the symptomatology in women attending a urodynamic clinic revealed that only 2.4% of them complained of stress incontinence alone [5].

Symptoms are unreliable

Research has shown that urinary symptoms inaccurately reflect the cause of lower urinary tract dysfunction. Bates et al (1970) coined the phrase "the bladder often proves to be an unreliable witness" and with good reason. In a study of 75 women

with recurrent incontinence, despite surgery for the symptom of stress incontinence, on formal urodynamic testing, 45 had DI without GSI, 30% had continuing GSI and 25% had no demonstrable urinary leakage [6 7].

Jarvis et al (1980) compared the results of clinical and urodynamic diagnosis for 100 women referred for investigation of lower urinary tract disorders [8]. The referring gynaecologist made a diagnosis of stress incontinence in 41 women and detrusor instability in 59 on the basis of their urinary symptoms alone. There was agreement in 28 cases (68%) of genuine stress incontinence and only 30 cases (51%) of detrusor instability. The study found that although nearly all the women with genuine stress incontinence complained of symptoms of stress incontinence, 46% of them also complained of urgency. Of the 35 women with detrusor instability, 26% complained of symptoms of stress incontinence.

Byrne et al (1987) found that even if the patients only symptom is stress incontinence, DI might still be present in 20% [9]. No major urinary incontinence was present though 45 (31.1%) women actually reported themselves incontinent at interview. It may be that factors other than the amount of urine lost determine whether an individual considers herself incontinent of urine or not.

Lagro Janssen et al (1991) showed that symptoms of stress incontinence in the absence of symptoms of urge incontinence had a sensitivity of 78%, specificity of 84% and a positive predictive value of 87% GSI [10]. Versi et al (1991) determined the accuracy of an analysis of symptoms alone for the diagnosis of GSI. Using the urodynamic diagnosis as the "gold standard", symptoms analysis achieved a correct classification of 81% with a false positive rate of 16% [11].

The clinical diagnostic accuracy of urinary symptoms in women when assessed by urodynamic studies is illustrated in table 5.1.

Accuracy of urinary symptoms	
Study	**Clinical Diagnostic Accuracy**
Jarvis et al (1980) [12]	76%
Glenning (1984) [13]	56%
Sand et al (1988) [14]	58%
Versi et al (1991) [15]	81%
Lagro-Janssen (1991)	87%

Table 5.1 Clinical diagnostic accuracy of urinary symptoms in women when assessed by urodynamic studies.

When the available published information at the time was combined by means of a meta-analysis, Jarvis (1984) found that the overall diagnostic accuracy of urinary symptoms in women with GSI was only 69.2%, while the overall diagnostic accuracy in DI is only 70.4% [16].

These observations are extremely important in a study designed to assess the effects of continence devices and quality of life impairment of women with GSI. Without a sound diagnosis it is impossible to compare the results of women with the same pathology and hopeless to perform any form of detailed assessment following intervention with continence devices. Despite these findings however the majority of similar studies to date have omitted to perform urodynamic investigations.

PHYSICAL EXAMINATION

Physical examination reveals information that is comparatively more objective, measurable and reproducible. It is performed complete and systematically but with particular reference to the lower urogenital tract. A good medical knowledge of urogenital tract dysfunction including pathophysiology and clinical manifestations of these conditions is also important.

GOOD URODYNAMIC PRACTICE

Urodynamic techniques vary from simple pad tests, frequency volume charts, "eyeball" urodynamics and ultrasound, to sophisticated synchronous multichannel computerised video/ pressure/ flow studies, ambulatory urodynamics and electromyography. Multichannel video urodynamics offers the most comprehensive artefact free way to arrive at the correct diagnosis, but is expensive and requires considerable manpower, expertise and time. The introduction of ambulatory urodynamics may provide an even more accurate method of evaluation but this is still unclear [17]. Regardless of the diagnostic strategies employed, appropriate diagnostic studies are selected and pursued until the nature, severity and cause of the disease is established. The aim of urodynamics is to reproduce the patient's symptoms under the condition of precise measurement in order to identify the underlying causes of the symptom and to quantify the related pathophysiological parameters.

It is a skilled procedure in terms of the appropriate selection of patients, setting up the equipment for each investigation and in the interpretation of the resultant pressure/flow recordings. A recent report on the causes, management and provision of services for incontinence recognised that urodynamics requires appropriately trained staff to perform and interpret the results [18]. Hosker et al (1997), to audit the provision of urodynamic services in the UK, sent out a questionnaire to 163 centres carrying out these tests [19]. They found no standardised training has been established to carry out urodynamics and no studies have investigated who carried out urodynamic investigations in the UK or the training that these personnel have received. Only half the respondents considered their training to be adequate even though they were responsible for investigating over 29,000 patients per year.

URODYNAMIC INVESTIGATIONS

Variation between measurement obtained by urodynamics is an important consideration as it may be a source of systematic bias. Discrepancy can be reduced by strict quality control such as good urodynamic practice and calibration of the instruments. Standardising the procedures in the study can also reduce variations. The ICS established a committee for the standardisation of urodynamic practice and terminology of lower urinary tract function in 1973. The standards are recommended to facilitate comparison of results by different investigators, especially when urodynamic methods are used [20]. Accurate interpretation depends on good equipment, correct placement of pressure lines and transducers, a standardised technique of performing each study and the presence of an experienced investigator with attention to good urodynamic practice. We work closely and abide by the codes of practice recommended by the International Continence Society.

LABORATORY DIAGNOSIS

The need for each test should be evaluated in terms of its sensitivity, specificity, predictive value, cost, safety and patient comfort. We need to determine which test should be performed, how does it clarify the patient's problem and what underlying pathophysiologic mechanisms of the disease will be explained by the test. Urodynamics are not without their problems. Benness and Manning (1997) have

shown that the majority of women experience discomfort during testing and in many, this continued following completion of the test and may even affect the performance of normal activities. Anxiety prior to testing and embarrassment during the studies were common. Pre-test information was appreciated by patients and despite these findings the vast majority of women felt that the investigations were acceptable and worth while [21].

Indications for urodynamics

- Women who complain of urgency prior to surgery for supposed GSI
- Women thought to have an unstable bladder but fail to respond to treatment
- Incontinent despite surgery for GSI
- Voiding difficulties
- Neurological abnormalities

I will describe, and included technical details, those urodynamic techniques that were employed to reach the correct diagnosis for women included in this study. The routine method of urodynamic assessment performed on patients attending our clinic will be described but more objective data will be provided in the chapter on outcome measures.

FREQUENCY VOLUME CHART

The frequency / volume chart is a specific urodynamic investigation recording fluid intake and urine output per 24 hour period, and ensures that clinical questions about frequency, nocturia and incontinence episodes can be accurately answered [23]. Elderly patients are often the most co-operative and accurate in their completion of the chart [22]. One practical consideration is that the chart involves the patient in the diagnosis of her condition and helps her to become an active partner in the treatment process.

PAD WEIGHT TEST

Verifying and quantifying incontinence by weighing perineal pads was initially proposed by Sutherst et al in 1981. This test was modified and accepted by the Standardisation committee of the International Continence Society in 1988 [23]. The pad test is a simple method of assessing urinary leakage [24 25].

UROFLOMETRY

Uroflometry is the measurement of the flow rate which represents the value in millilitres of urine expelled from the urethra in unit time. It characterises abdominal activity, detrusor contractions and urethral relaxation. Measurement of urine flow provides an objective assessment of voiding ability. Uroflometry is rapid, non-invasive, physiological and requires little specialist equipment apart from a commode and a flow meter. It allows the measurement of voided volume, maximum flow rate, acceleration of flow rate, average flow rate, flow time and time to maximum void.

The three main parameters of interest are flow rates, flow patterns and volume recordings. It is important to get a "representative" flow pattern with the subject relaxed and comfortably full. Difficulties arise if the woman is anxious or the bladder is too full and over-stretched and the detrusor temporarily decompensates. Flow is also age and volume dependent [26]. In women, a normal flow rate in a full bladder, which empties completely, excludes obstruction [27].

Many high flow rates of up to 40ml/s do not always indicate good detrusor function. It may be seen in women with long standing detrusor instability and neurogenic bladder dysfunction.

Nomograms have been established to provide a normal reference range for the maximum and average urine flow rates over a wide range of voided volumes for both men and women [5]. The characteristic of the trace or the patterns seen may be indicative of certain conditions. Normal female voiding produces a bell-shaped curve on uroflometry. Voiding dysfunction may give rise to an intermittent or multiple peaked flow. A low flow rate may be due either to bladder outlet obstruction, detrusor sphincter dyssynergia (DSD), or impaired detrusor contractility. Simultaneous cystometric recording of detrusor pressure during voiding can be performed in such cases to exclude detrusor dysfunction and urethral pressure profilometry and sphincter EMG to evaluate outflow obstruction. Obstruction may take the form of high pressure/low flow voiding or normal pressure/low flow voiding. In a review of obstructed voiding in women the incidence of obstruction was approximately 2.7% (excluding DSD and overt neuropathy) [28]. In general terms, there are no symptoms or group of symptoms in women except retention which are diagnostic of outlet obstruction. Detrusor instability may give rise to a high peak flow attained rapidly within the first few seconds, a short voiding cycle and the flow

returns to zero with a rapid fall. A long voiding cycle with a low peak and average flow is characteristic of outflow obstruction. Detrusor failure may give rise to a similar tracing so a diagnosis on the basis of flow rate alone is not possible.

CYSTOMETRY

Cystometry is a method by which the pressure volume relationship of the bladder is measured. It is used to assess detrusor contractility, sensation, capacity and compliance. The International Continence Society has established detrusor classifications of normal, hyperreflexic or hyporeflexic based on the results of cystometry [23]. Normally cystometry is performed with the patient supine, but the patient may be seated or standing. A change in posture during cystometry is provocative and is used to test for detrusor instability.

Filling Medium

Generally cystometry is performed using a liquid radiological contrast medium called urografin, kept at room temperature. Filling is conducted with the subject supine and once the bladder is full the patient is brought to the erect position by tilting the X-ray table.

Filling Rate

Although there are many techniques for performing cystometry the most commonly used method is retrograde filling of the bladder with fluid at a constant rate, measuring the intravesical pressure and generating a pressure / volume curve of the results. A filling rate of 100 ml/min (fast fill cystometry) is 60 times the normal physiologic rate. Often a slower filling rate of 30 ml/min is appropriate for patients with suspected detrusor hyperreflexia. Medium fill cystometry is employed in our unit with a fill rate of 50ml per minute.

Measurement of intravesical pressure

Intravesical pressures can be measured directly with microtip transducers, or via a manometer system connected to an external transducer placed at the level of the superior edge of the symphysis pubis. Simultaneous measurement of abdominal pressure by means of a rectal or vaginal transducer allows calculation of the detrusor pressure by electronic subtraction of the intra-abdominal from the intravesical pressure recording. The calculation of detrusor pressures in this manner results in far more reproducible investigations less susceptible to artefact errors.

Filling Study

The vulval and urethral meatus are cleansed with Savlon and the urethra is lubricated with gel. The pressure line is introduced piggy-backed to the filling catheter with its tip in the side hole of the filling catheter. Once the filling catheter is in the bladder, the pressure line is disconnected by pulling back sharply with the filling line held still. The filling line is further advanced so as to coil within the bladder. Both tubes are held in place with adhesive tape onto the inner thigh. The filling catheter is first allowed to drain into a bowl to ensure the bladder is empty prior to the start of the test and to measure the residual volume.

Rectal Catheter

Rectal pressure is thought to accurately reflect intra abdominal pressure. We use ready prepared fine 5F fluid filled tubes with side holes to measure pressure. Faecal occlusion is prevented with a rubber covering with a split to allow transmission of pressures. The top is also lubricated and the catheter introduced completely into the rectum well beyond the anal sphincter. If it is too low it will record sphincter contractions and interfere with the subtracted detrusor pressure.

If the patient can not tolerate a rectal catheter, the intra abdominal pressure is approximated using a transducer placed in the vagina. Rectal pressure and vaginal pressure are not the same but are reasonable approximations of each other during filling and voiding cystometry [29].

Cystometric examination

Filling Phase

Once filling and pressure recordings have begun the woman is asked to cough. This acts as a potential provocative stimulus and is performed at the start and at every 100ml of fluid instilled in the bladder. The patient is asked to report the first sensation to void, any urgency or leakage and bladder fullness. All events are recorded on the trace. Video radiographic screening is not normally recorded during the filling phase. However, in the event of detrusor over-activity, the subject is screened at that time to observe the bladder morphology, urge incontinence and the presence and grade of any vesicoureteric reflux. At the end of this phase the filling line is removed. Bladder compliance is a measure of the degree of stiffness of the detrusor muscle wall and indicates the change in volume for a unit change in pressure. At a filling rate of up to 100 ml/min the vesicoelastic and geometric properties of the bladder prevent a rise in vesical pressure of more than 15 cm H_2O. This is considered to be normal bladder compliance (Figure 3.2).

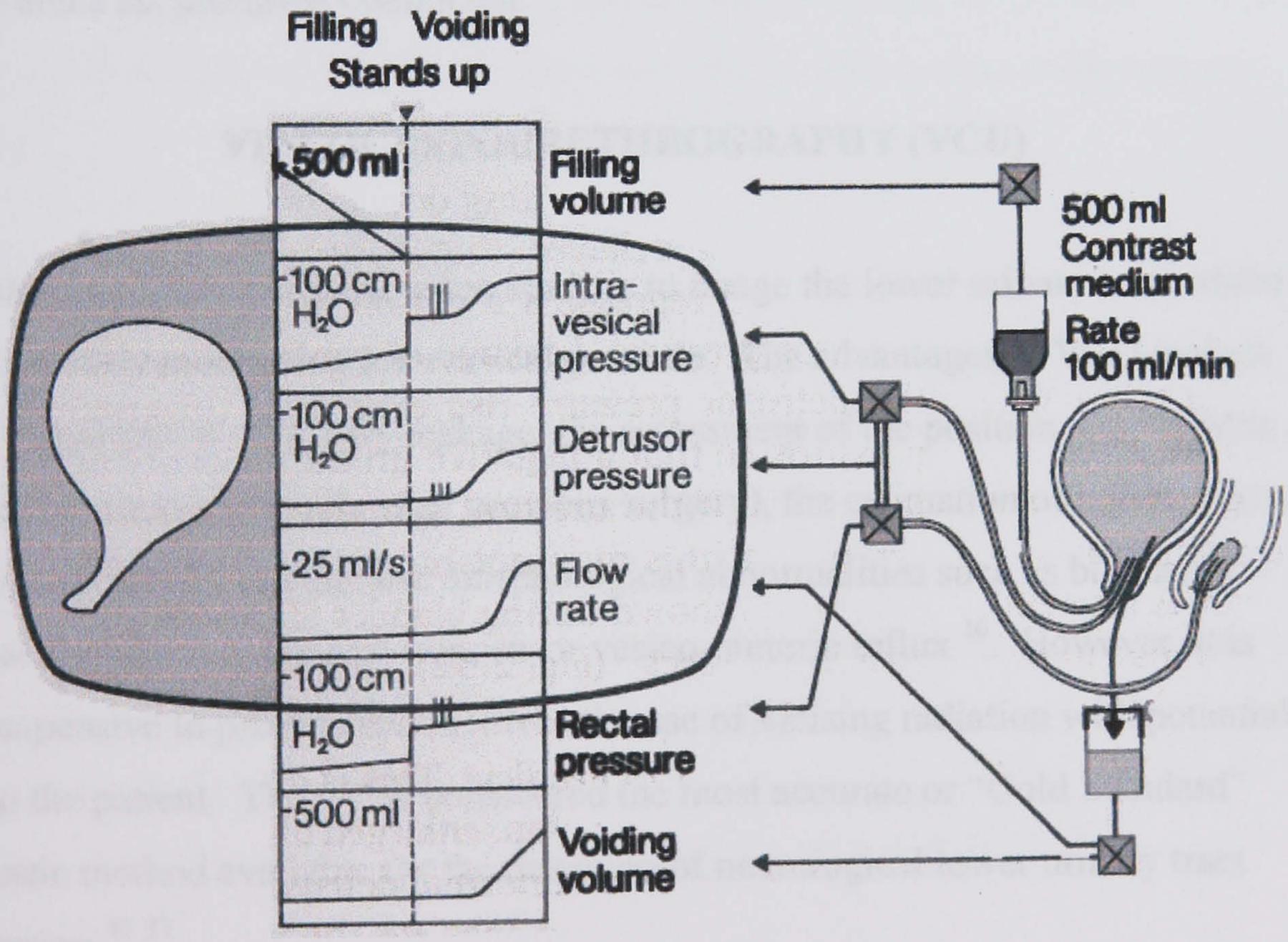


Figure 3.2. Normal Videocystometrogram.

Voiding Phase

When cystometric capacity has been reached, filling is stopped and the filling catheter removed. It is usual to ask the patient to stand and cough several times to check once again for leakage due to provoked detrusor instability and genuine stress incontinence.

The patient is asked to void into the flow meter with the pressure lines in situ. The transducers are adjusted so that they are at the level of the symphysis. The subject is left in privacy and a pressure flow plot is obtained on the trace.

The course of micturition depends on both bladder contraction strength and urethral resistance [30]. The maximum detrusor pressure during voiding is a result of contraction of the bladder against the resistance of the urethra. Normally voiding occurs by coordinated contraction of the detrusor and relaxation of the urethral sphincter; the urethral sphincter relaxing before the onset of detrusor activity. Factors which may affect detrusor contraction strength include the age of the subject, voided volume, the presence of detrusor instability and previous pelvic surgery [31]. Any residual volume is assessed by comparing the filled and voided volume.

Once the procedure is completed, the cystometry trace is marked with the patient details and a set proforma completed.

VIDEOCYSTOURETHROGRAPHY (VCU)

The purpose of the combined video study is to image the lower urinary tract whilst simultaneously monitoring intravesical pressure. The advantages of VCU include easier visualisation of urinary leakage, the assessment of the position and mobility of the bladder neck (especially after previous surgery), the estimation of residual urine and the opportunity to diagnose morphological abnormalities such as bladder or urethral diverticulae, urethral stenosis or vesico-ureteric reflux [16]. However, it is more expensive to provide and involves the use of ionising radiation with potential risks to the patient. The test is considered the most accurate or "Gold Standard" diagnostic method available for the detection of neurological lower urinary tract dysfunction [32 33].

URETHRAL PRESSURE PROFILE

We are aware that little effort is required to overcome the urethral resistance of women with severe GSI compared to women with less severe incontinence. Hilton and Stanton (1983) suggested it is reasonable to assume that the magnitude of the compromise in urethral resistance is correlated with the severity of the individual patient's incontinence [34]. The urethral pressure profile (UPP) is a plot of pressure against distance obtained by withdrawing a pressure recording transducer from the bladder through the urethra at a constant speed. The UPP is obtained at rest and during a series of coughs. These transducers measure a stress component at right angles to their surface rather than hydrostatic pressure and therefore measurements will be affected by their orientation within the urethra. The urethral pressure recorded is maximum with the transducer facing anteriorly and minimum with it facing posteriorly. As a compromise the transducer may be used in either the 3 or 9 o'clock position which provides an average measurement.

The static or resting urethral profile is the intraluminal pressure along the length of the urethra with the bladder at rest. The UPP trace shows a low-pressure value in the bladder, which gradually rises from the bladder neck, through the proximal urethra, is maximum in the mid-urethra, from where it gradually falls to zero at the external meatus.

Stress UPP

The urethral pressure profile is performed with a subjectively full bladder with the patient in the supine position. The transurethral catheter is withdrawn through the urethra at a rate of 0.5 mm/second using a mechanical pulley system. The patient coughs repeatedly during the test. Pressure transmission ratios are calculated for each cough spike during the stress UPP using the formula:

$$\text{Pressure transmission ratio} = \frac{\text{Change in urethral pressure}}{\text{Change in vesical pressure}} \times 100$$

The pressure transmission ratios are calculated for every cough and averaged for each one-third of the functional urethral length (proximal, middle and distal). If a positive area remains under the pressure profile curve with any cough the test is considered negative. If pressure equalisation occurs with each cough throughout the length of the urethra, then the test is considered positive [35]. The presence or absence of urine loss during the test is also noted.

COMMONLY USED URODYNAMIC TECHNIQUES

The following is a list of commonly used urodynamic techniques and urodynamic variables which can be detected and interpreted during the various investigations.

Filling CMG

Residual urine

Abnormal detrusor pressure rise

- ⇨ symptomatic
- ⇨ tonic
- ⇨ phasic
- ⇨ provoked or systolic

Atonic detrusor

Bladder capacity

Fluoroscopy

- Competent sphincter
- Descent and rotation of bladder neck – degree, severity
- Incompetence related to detrusor or abdominal pressure rise
- Ballooning of urethra
- Urethral diverticulum
- Fir tree bladder
- Conical bladder
- Trabeculation or diverticulae
- Fistulae
- Vesicoureteric reflux

- ⇨ spontaneous
- ⇨ related to bladder over-activity

Abnormality of the bony pelvis

Voiding CMG

Bladder

- ⇨ can initiate a detrusor contraction
- ⇨ sustained contraction
- ⇨ pressures attained
- ⇨ isometric contraction on "stop-test"
- ⇨ strain to void
- ⇨ good correlation between uroflometry and flow during voiding CMG

Outflow tract

- ⇨ Obstruction
- ⇨ Detrusor Sphincter Dyssynergia

Normal Study

- Bladder capacity: 400 – 500ml
- 1st sensation: 150ml
- 1st urge to void: 350ml
- Detrusor rise on filling: < 15cm H_2O for a volume of 500ml
- Free Flow Rate: > 15ml/sec for a volume of 150ml
- Voided Volume: > 150ml

Detection of the presence of GSI

- ⇨ Bladder base descent
- ⇨ Degree of bladder neck descent
- ⇨ Stable CMG
- ⇨ Severity of sphincter incompetence
- ⇨ Anatomical assessment of dynamic changes associated with GSI
- ⇨ Rigid "drain pipe" urethra associated with failed continence surgery

Sensory urgency

- ⇨ Painful catheterisation
- ⇨ Early 1st sensation
- ⇨ Reduced bladder capacity: (<350ml)
- ⇨ Stable bladder

Hypo contractile bladder

- ⇨ minimal "flat" detrusor activity
- ⇨ large capacity bladder
- ⇨ little sensation of bladder filling
- ⇨ strain to empty with poor or intermittent flow pattern
- ⇨ significant residual

Poor Detrusor Compliance

- Slow rise in intravesical pressure on filling CMG, associated with urgency
- The pressure rise subsides when filling is stopped

EQUIPMENT USED

The same equipment was used for all of the investigations carried out in this thesis and was maintained by the Department of Medical Physics at King's College Hospital.

Uroflometry

Uroflometry was performed using an RS component load cell and strain gauge amplifier to weigh the voided fluid. The equipment was checked prior to each investigation session for calibration with zero mls and 500 mls of water. The volume signal was differentiated electronically to give the flow rate signal.

- Volume Range; - - 1800 mls
- Accuracy; +/- 1 ml
- Flow rate range; 0 – 100 ml/s
- Accuracy; +/- 2%

Subtracted cystometry

Subtracted cystometry was performed with water filled pressure lines connected to Spectramed P23XL pressure transducers situated at the level of the superior border of the symphysis pubis (Range – 5 cm H_2O to + 100 cm H_2O; Accuracy +/- 3%). The equipment was calibrated prior to each investigation session; zero was set at the level of the symphysis pubis and the gain was set to a 50cm column of water. Recordings were made on a Neomedex Aquadata computerised recorder where the infused volume, rectal pressure, intravesical pressure, detrusor pressure and flow rate could be simultaneously shown. A paper speed of 5 cm/min was used for filling cystometry and 15 cm/min for uroflometry and voiding cystometry.

Urethral Pressure Profilometry

Urethral pressure profilometry was performed using a 7 French silicone coated Gaeltec 16CT/S-2 dual sensor catheter with two microtip pressure transducers set 6cm apart. The catheter was calibrated prior to each investigation session (zero to 100 cm water). The withdrawal device was a Wiest CP 4302N puller.

CONCLUSION

The following is the protocol for assessment of lower urinary tract dysfunction used in Prof. Cardozo's unit and applied in this study.

(i) On arrival a detailed urinary and medical history is taken, including a symptom questionnaire and visual analogue chart completed by the patient.

(ii) A thorough pelvic examination.

(iii) Uroflometry is performed

(iv) Subtracted cystometry and videocystourethrography is performed.

- Voiding is then commenced over a flow meter and additional imaging is performed. The patient is asked to interrupt their urinary stream and further imaging is performed.
- The pressure catheters are removed, the patient is asked to empty their bladder and radiological assessment of any urinary residual is made.

Often this assessment is adequate for the evaluation of the incontinent patient. Complex cases however require further investigation.

(v) Urethral pressure profilometry is performed on patients with evidence of voiding difficulties, previous failed incontinence surgery, evidence suggestive of a urethral diverticulum or urethral stricture and patients with a diagnosis of both detrusor instability and urethral sphincter incompetence.

(vi) Patients with normal findings but symptoms of incontinence are offered a pad-weighing test.

(vii) Ambulatory urodynamics is available for the assessment of patients with a history of incontinence but both a negative pad test and normal videourodynamics.

References

[1] Fourcroy J. Urogynaecology update: incontinence. Hosp Pract (Office Ed) 1998; 33(5):63.70.

[2] Cutler P. Problem solving in clinical medicine. 2nd Ed. Baltimore, Williams & Wilkins 1985.

[3] Blacklow RS : MacBride's Signs and Symptoms. 6th Ed. Philadelphia, JB. Lippincott & Co; 1983.

[4] Griner P, Glaser R. Misuse of laboratory tests and diagnostic procedures N Engl J Med 1982;307:1336.

[5] Haylen B, Frazer M. Is the investigation of most stress incontinence really necessary? Neurourol Urodyn. 1987;6:37.

[6] Bates C, Whiteside C, Turner-Warwick R. Synchronous cine/line pressure / line flow / line cystourethrography with special reference to stress and urge incontinence. Br J Urol 1970;42:714-723.

[7] Bates C, Loose H, Stanton S. The objective study of incontinence after repair operations. Surg Gynecol Obstet 1973;136:17-22.

[8] Jarvis G, Hall S, Stamp S, Millar D, Johnson A. An assessment of urodynamic examination in incontinent women. Br J Obstet Gynecol 1980;87:893-96.

[9] Byrne D, Stewart P, Gray B. The role of urodynamics in female urinary stress incontinence. Br J Urol 1987;59:228-29.

[10] Lagro-Janssen A, Debrugne F, VanWeel C. Value of the patient's case history in diagnosing urinary incontinence in general practice. Br J Urol 1991;67:569-72.

[11] Versi E, Cardozo L, Anand D, Cooper D. Symptoms analysis for the diagnosis of genuine stress incontinence. Br J Obstet Gynecol 1991;98:815-19.

[12] Jarvis G, Hall S, Stamp, Millar D, Johnson A. An assessment of urodynamic examination in incontinent women. Br J Obstet Gynecol 1980;87:893-6.

[13] Glenning A. Clinical symptoms and urodynamic assessment. Aust NXJ Obstet Gynecol 1984;24:95-7

[14] Sand P, Hill R, Ostergard D. Incontinence history as a predictor of detrusor instability. Obstet Gynecol 1988;71:257-80.

[15] Versi E, Cardozo L, Anaud D, Cooper D. Symptom analysis for the diagnosis of genuine stress incontinence. Br J Obstet Gynecol 1991;98:815-9.

[16] Jarvis G. Female urinary incontinence – which patients? – which tests? In the Yearbook of the Royal College of Obstetricians and Gynaecologists 1984. Studd J, ed.

[17] Wein A. Ambulatory bladder monitoring: is it an advance? J Urol 1998: 160(6 pt 1): 2310-1.

[18] Incontinence: causes, management and provision of services. Royal College of Physicians of London 1995.

[19] Hosker G, Kilcoyne P, Lord J, Smith A. Urodynamic services, personnel and training in the United Kingdom. Br J Urol 1997;79:159-162.

[20] The standardisation of terminology of lower urinary tract function. Br J Obstet Gynecol 1990;Suppl 6:1 – 16.

[21] Benness C, Manning J. Patient evaluation of urodynamic investigations. Neurourol Urodyn 1997;16(5):509-510.

[22] George N, Barnard R, Blacklock N. Frequency / volume charts revealing physiological abnormalities. Proceeding of the 11th Annual Meeting of the International Continence Society 1981, p 67 – 68.

[23] Abrams P, Blaivas J, Stanton S, Andersen J. The standardisation of terminology of lower urinary tract function. Scand J Urol Nephrol 1988;Suppl 114:5-19.

[24] Victor A. Pad weighing tests – a simple method to quantify urinary incontinence. Ann Med 1990;22:443-7.

[25] Wyman J, Choi S, Harkins S, Wilson M, Fantl J. The urinary diary in evaluation of incontinent women: a test-retest analysis. Obstet Gynecol 1988;71:812-17

[26] Haylen B, Parys B, Anyaegbunam W, Ashby D, West C. Urine flow rates in male and female urodynamic patients compared with the Liverpool nomograms. Br J Urol 1990;65:483-487.

[27] Stephenson T. The interpretation of conventional urodynamics. In Urodynamics, principles, practice and application. Eds. Mundy A, Stephenson T, Mein A. Churchill Livingstone London, UK 2nd Edition 1994.

[28] Massey J, Abrams P. Obstructed voiding in the female. Br J Urol 1988;61:36-39.

[29] Wall L, Hewitt J, Helms M. Are vaginal and rectal pressures equivalent approximations of one another for the purpose of performing subtracted cystometry? Obstet Gynecol 1995;85(4):488-93.

[30] Groen J, Van Mastright R, Bosch R. Neurogenic modulation of micturition: the relation between stimulation intensity and the maximum shortening velocity of the guinea pig detrusor muscle. J Urol 1995;153(1):228-32.

[31] Karram M, Partoll L, Bilotta V, Angel O. Factors affecting detrusor contraction strength during voiding in women. Obstet Gynecol 1997;90:723-726.

[32]Bates C. P., Corney L. E. Synchronous cine pressure cystography: a method of routine urodynamic investigation. Br J Radiol, 1971; 44:44-50.

[33]Blaivas J.G., Fisher D.M. Combined radiographic and urodynamic monitoring. Advances in techniques. J Urol 1981; 1 25: 693-694.

[34] Hilton P, Stanton S. Urethral pressure measurement by microtransducer: the results in symptom free women and in those with genuine stress incontinence. Br J Obstet Gynaecol 1983;90:919-33.

[35] Theofrastous J, Bump R, Elser D, Wyman J, McClish D and the Continence Program for Women Research Group. Am J Obstet Gynecol 1995;173:407-14.

CHAPTER SIX

PATIENTS AND METHODS

INTRODUCTION

A given therapeutic approach must stand up to the rigors of comparison studies before it can be deemed effective. Often therapies are widely adopted into clinical practice before such evaluation has occurred. Descriptive cases although a popular method for clinical investigation, do not account for any placebo effect or change in any individual's condition over time. The only valid method for determining clinical effect comes from comparison studies. Study designs which allow such comparisons include cohort studies and case-control studies.

In the description of the design of the study I wish to formulate the aims of the investigation, state the methodology used, how the sample population was recruited, and determine the criteria for the disease being measured. The nature of interventions to be tested, conditions of administration and assessment and interpretation of outcome will be summarised. The inclusion and exclusion criteria used will be defined and the statistical methods utilised will also be outlined.

A discussion of the choice of outcome measures selected and techniques of measurement as well as the methods of analysis of treatment effect will be given in subsequent chapters. In the design of the study we also defined the criteria for a complete or maximum response, improvement and deterioration.

THE PURPOSE OF THE STUDY

In defining the objectives of continence devices one is really characterising the reasons for this specific study and what we as investigators want to show. This thesis attempts to present the best available evidence to support the use of continence devices for the symptom of stress incontinence in women. In simplest terms, the objectives of continence devices are the improvement or cure of the symptom of stress incontinence. But there are other secondary objectives at different levels, involving the individual, her family, community and society as a whole, which are not explicitly defined.

The primary objective is to study the clinical efficacy,acceptability and safety of the Reliance Urinary Control Insert and the FemAssist Incontinence Device in the management of women with objectively demonstrated urinary incontinence.

The secondary objective is to study the effect of the introduction and use of novel non-surgical treatment options for women with urinary incontinence on their quality of life.

RECRUITMENT

STUDY POPULATION

Women with a history of urinary incontinence, referred for assessment to King's College Hospital (KCH) Urogynaecology Department were considered for entry to the study. In taking a sample from this population, we examine this subgroup in detail so inferences can be drawn about the whole population. There are a number of different ways of obtaining a random sample but all have the following in common – the results can be generalised to the total population from which the random sample was derived and probabilities calculated for possible effects and differences between the unknown true value and the value obtained from the sample.

The sampling frame was all women referred with the symptom of stress incontinence. As a sampling frame representative of the general population I recognise that this has earnest limitations. In conditions such as stress incontinence a proportion of women afflicted will not make the decision to seek health care even though they may recognise themselves as incontinent. A further proportion will visit their GP only whilst others will come to the attention of hospital services as outpatients or inpatients. The processes which lead to this are complex and depend on many factors such as: the woman's perception of her ill health, her own attitudes and those of her family, friends and society in general to illness and the availability of continence services. Thus, a certain unknown proportion of women are already excluded i.e. women who are not in contact with the Health Services and have incontinence but do not seek treatment.

DEFINITION OF INCONTINENCE

Urinary incontinence is defined as the "involuntary loss of urine which is a social or hygienic problem and objectively demonstrable"[1]. It is a symptom and not a disease.

Genuine stress incontinence is defined as an involuntary loss of urine when the intravesical pressure exceeds the maximal urethral pressure in the absence of a detrusor contraction. Strict criteria must be fulfilled in order that a woman is counted as having GSI. In previous studies on the efficacy of devices it was not always apparent what the criteria were. It is essential to adhere to a working definition or the results collected will have no meaning outside the context of this clinical trial. The definition of intrinsic sphincter deficiency (ISD) remains unclear and its significance in the management of incontinence remains elusive and a definition based on reproducible quantitative urodynamic parameters and physical examination is lacking [2]. Hence, no distinction or stratification was made of women having ISD as the cause of GSI.

There is no agreed standard criterion for making the diagnosis of GSI, so there is still confusion about which technique can best provide an accurate diagnosis in the patient suspected of having GSI [3]. The techniques range in complexity from a cough stress test or observation of urine leakage from the external urethral meatus during a cough, cough UPP, a one, two or 48 hour pad test to video-cystourethrography involving multichannel urodynamic pressure studies with simultaneous fluoroscope examination of the lower urinary tract. The data from the study by Swift and Ostergard (1995) showed that no single test is 100% sensitive or specific for deleting GSI. Observed loss with a cough during multichannel urodynamics was the best individual predictor of GSI. In women with pure GSI, a positive cough stress test with a negative preceding cystometrogram was close to being 100% sensitive and specific. This is the most reliable predictor of GSI and if it is negative, then the diagnosis of GSI should be questioned.

Rigorously defined clinical criteria are highly reliable in predicting the presence of GSI at the time of urodynamic testing. Nidela and Wall (1998) found that if a woman has the following:

- predominant complaint of stress incontinence
- positive cough stress test result
- post-void residual urine volume of less than 50ml
- a functional bladder capacity of at least 400ml as determined by a completed 24 hour frequency/volume chart,

- then GSI could be predicted in 72 (97%) of 74 patients [4].

These criteria together with observed loss on coughing during multichannel videocystourethrography and a negative cystometrogram were used in this study to detect GSI. For the assessment of the devices, a mean of two or more incontinence episodes per day was chosen as the event rate signifying the presence of moderate or worse stress incontinence. Based on pad weight test gains, a urine loss of 2g/h or more was classified as incontinent (according to the ICS) [1]. A mean PWT gain of less than or equal to 1g was considered to signify continence.

INCLUSION CRITERIA

- Women with a history of urinary incontinence.
- Women capable of understanding and having signed the informed consent after full discussion of the research nature of the therapy and the potential for adverse events.
- Women with urodynamically proven GSI.
- Mobile women able to attend an outpatient clinic.

EXCLUSION CRITERIA

- Women with any disease which in the opinion of the investigator makes her unsuitable for inclusion.
- Women with conditions contra-indicating daily introduction of a catheter-like device into the urethra.
- Women who are pregnant or considering pregnancy.
- Women with recurrent urinary tract infections (RUTI's) defined as treatment for UTI on 3 or more occasions in the last year.
- Women with symptomatic acute urinary tract infections (UTI) during the run-in period.
- Women with uninvestigated haematuria or haematuria secondary to malignant disease.
- Any drug therapy for urinary urge incontinence, with the exception of any oestrogen therapy.
- Women who have received any electrostimulation therapy or bladder training within the last 14 days or who expected to start such therapy during the study period.
- Women aged greater than 80 years or less than 18 years.

DEVICE ALLOCATION

Once women satisfied the inclusion criteria they were selectively allocated to one or other of the devices by alternating the type of device for the next subject. The study was non-blinded and the women acted as their own controls. I did not stratify the data according to age groups or degree of incontinence although this may have helped to ensure adequate representation of these different sections of the population. This was restricted due to the time constraints and resource limitations on the trial. On four occasions patients were incorrectly allocated the FemAssist device, hence the discrepancy in the numbers recruited to each group.

PATIENT CHARACTERISTICS

Demographic information, particularly related to the patients' age, race and family history, knowledge of the prevalence and the geographic distribution of the disease process are all commonly employed to exclude or confirm certain diagnostic possibilities. Because of the potential for co-morbidity in women over the age of 65, all women being considered for entry to the study were assessed for co-existing medical conditions and factors such as faecal impaction, confusional states, functional disabilities, hypertension and particular reference to the use of medications which may contribute to incontinence or might affect the outcome of the study. The following baseline characteristics were recorded for all women:

- Demographic Data: Date of birth
  Weight
  Height
  Ethnic Origin
- Urodynamic investigation
- Disease history, primarily considering the lower urinary tract
- Continence surgery
- Type of urinary symptoms
- Previous treatment for incontinence and the results regarding efficacy and adverse events
- Present status of the woman

- Concurrent diseases and symptoms

All concomitant medication taken by the patient were recorded together with administration form, dose, frequency, start date and, when applicable, stop date at each visit.

THE INTERVENTION

FEMASSIST URINARY INCONTINENCE DEVICE

FemAssist Urinary Incontinence Device is a cap-shaped device, composed of silicone rubber. Patients were taught to place it directly over the urethra where it will be held in place by its own mild vacuum action (Figure 6.1). A small amount of lubricating gel was placed on the surface which comes in contact with the body. This helps maintain the vacuum seal and protects against accidental urine loss. When the woman wishes to void, she removes the device by pulling the base away from the urethra. The device should then be cleaned with soap and warm water and replaced over the urethra. The device should be disposed of at the first signs of wear or after 7 days. The device was sold by the manufacturer in boxes of four at a cost of £30.

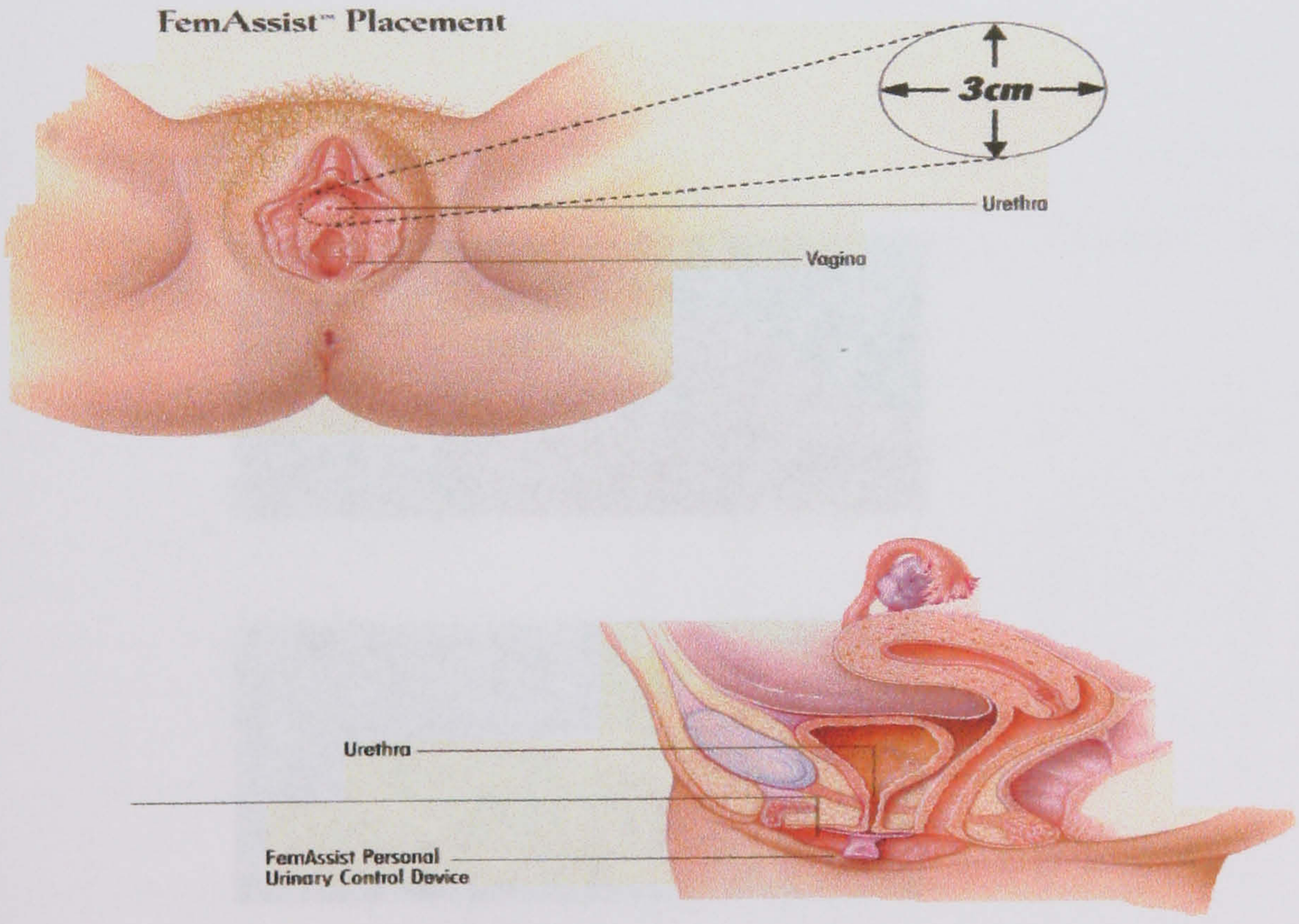


Figure 6.1 Placement of the FemAssist continence device.

The intervention related complications, morbidity, risks and hazards associated with the devices have been described in detail in the chapter on continence aids.

Women were trained in the safe use and method of use of each of the devices by the specialist nurse practitioner and myself.

RELIANCE URINARY CONTROL INSERT

This device is composed of non-toxic, thermoplastic material and comprises an oval meatal plate, a soft stalk and one sphere located at the distal end of the stalk. There are five sizes available and each subject was measured for the best fit (Figure 6.2).

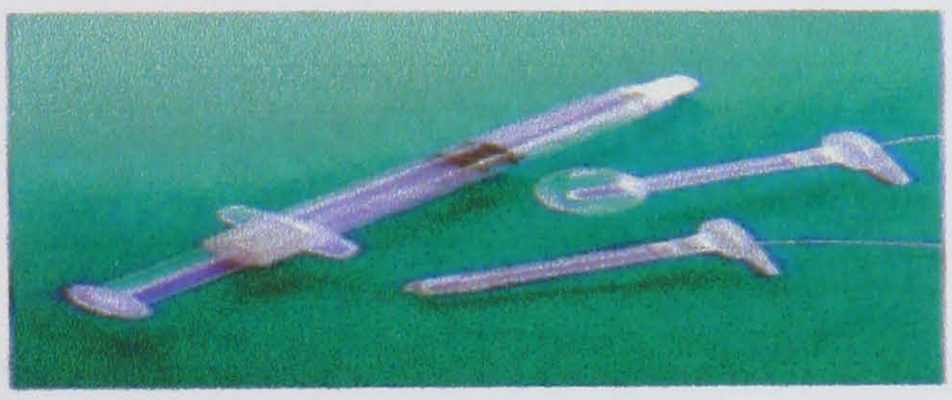


Figure 6.2 Five sizes of the Reliance device.

Patients were instructed in the method of how to gently insert the device into the urethra. Then a small balloon at the tip of the device is inflated, using a syringe-like applicator, to block the bladder neck opening and prevent the flow of urine (Figure 6.3). The applicator is then removed, and the device remains comfortably in place as the bladder fills normally. When the woman desires to go to the lavatory, a simple tug on the device's string will deflate the balloon, allowing her to easily remove it. After urinating, she simply inserts a new Reliance.

Women were given advice to use the device as they felt necessary and to adjust the timing and number used to accommodate their particular lifestyle and life events. The device was sold by the manufacturer in boxes of 50 at a cost of £50.

No prophylactic antimicrobial therapy was used at any time during the study.

TREATMENT SCHEDULE

Visits were required at base line, after one, three and six months follow-up or whenever the woman was withdrawn. Any adverse events present at the end of the treatment were followed for at least 2 weeks.

The investigations that were performed during the study are in the table 6.1.

Schedule of events				
Recordings/Measurements	**Baseline**	**1Month**	**3Months**	**6Months**
Written informed consent	X			
Inclusion & exclusion criteria met	X			
Demographic data	X			
Disease history	X	X	X	X
Previous drugs for urge incontinence	X			
Concurrent disease or symptoms	X	X	X	X
Concomitant medications	X	X	X	X
Blood pressure & physical examination	X	X	X	X
Assessment of urinary diary	X	X	X	X
Quality of life profile	X			X
Patient self-assessment	X	X	X	X
Weighted pad test	X	X	X	X
Mid stream specimen of urine	X	X	X	X

Table 6.1 Schedule of investigations that were performed during the study.

Differences in outcome can be expected depending on the time chosen for assessment in relation to the intervention. Short and long term results might be different. The outcome was evaluated after 6 months duration of therapy. We do not know what would be ideal. Whatever one chooses, if the subject was not in a stable phase at the time of assessment, further improvement or deterioration could be expected but not predicted.

The following is a copy of the informed consent and information leaflet given to each patient at entry to the trial.

INFORMED CONSENT

- Doctor Boos has explained to me the advantages and disadvantaged, the risks and the discomforts of the study. I have read the information, and I have had the opportunity to ask questions. I have had enough time to think it over. I understand the nature and the purpose of the study.

- I understand that participating in this study is voluntary and that I can decide to withdraw without any reason given. This will not influence my further treatment and the relation with my doctor.

- I know that for this study relevant medical data about me will be used for scientific study and for a possible publication. Herewith I agree, as long as my privacy is safeguarded.

- I agree voluntarily to participate in this study.

Patient's Name: .....

Date: ..... Date: .....

....

Patient's signature Investigator's signature

PATIENT INFORMATION

Dear Patient,

You are invited to participate in a clinical study involving the Reliance Urinary Control Insert and FemAssist Urinary Incontinence Device which are intended to act as a temporary barrier to keep urine from leaking out of the bladder until you are ready to go to the lavatory.

A Reliance device is gently inserted into the urethra (outlet to the bladder). Then a small balloon at the tip of the device is inflated, using a syringe-like applicator, to block the bladder opening and prevent the flow of urine. The applicator is then removed, and the device remains comfortably in place as the bladder fills normally.

When you desire to go to the lavatory, a simple tug on the device's string will deflate the balloon, allowing you to easily remove it. After urinating, you simply insert a new Reliance.

For Reliance to work most effectively, your urethra will be measured by your doctor to ensure that the proper size is given to you. You will then be provided with Reliance devices tailored to your personal needs. You will also receive an applicator for properly inserting and inflating the Reliance devices.

The FemAssist is a cap-shaped device, composed of silicone rubber. It is designed to be placed directly over the urethra where it will be held in place by its own mild vacuum action.

A small amount of sealing lubricating gel is placed on the surface which comes in contact with the body. This helps maintain the vacuum seal and protects against accidental urine loss. The device stays in place for as long as is comfortable. When you wish to pass urine, you remove the device by pulling the base away from the urethra. The device should then be cleaned with soap and warm water and replaced. The device should be disposed of at the first signs of wear or after 7 days.

You may feel a bit nervous the first few times you practice using your device. This is perfectly normal. Just as inserting a tampon takes most women a few tries before it becomes a natural activity, all you need is some experience using a continence device before it becomes a simple and easy part of your daily routine. A series of activities has been carefully designed to familiarise you with how to use your device, starting outside your body so that you become completely comfortable with handling the device and its applicator before you begin using them in 'real life'. This will help you gain experience and build your confidence. Step-by-step instructions will be given to you by your Doctor and specialist Nurse.

WHAT WILL HAPPEN DURING THE STUDY?

You will be selectively allocated to use one of the two devices at the start of the study. We need to follow your progress over 6 months. This means that we will ask you to come to the centre at 1, 3 and 6 months during the study. Before the treatment is started you will be asked a few questions about your disease and general condition. At each visit we will measure your blood pressure and perform a physical examination. A mid-stream sample of urine will be taken and a pad weight test performed at each visit. The pad weight test will be made clear to you and explained in detail by the doctor before each visit. You will also be required to complete a urinary diary and a brief Quality of Life questionnaire.

WHAT RISKS ARE INVOLVED?

In previous studies both devices were well tolerated and no serious side effects were seen. The incidence of adverse events is well within the range expected with other commonly accepted self-catheterization techniques. Moreover, these events tend to decrease in frequency overtime. Study results indicate that there is a learning curve with use of the insert. Women become more comfortable with the devices as they gain experience with continued use.

WHAT ARE THE BENEFITS?

The results of clinical studies of these devices in women demonstrated that use is an effective means of managing urinary stress incontinence. Objective and subjective data indicate that women also experienced a significant improvement in their quality of life.

Overall, there is high user satisfaction with both devices as an early non-surgical, non-implantable option in the control of urine leakage in stress incontinence.

However, if you experience any adverse effects or other discomfort during the study it is important that you inform your doctor as soon as possible.

CONFIDENTIALITY

Your family doctor will, if applicable, be informed of your study participation. The results of your treatment will be recorded on special forms. Your data will be stored confidentially and analysed after the study. The results of the study may be inspected by the Department of Health and authorised persons but confidentiality will always be maintained. The study is approved by the Medical Ethics Committee of your hospital.

Your participation in this study is entirely voluntary. If you feel that you do not want to take part, just say so. Should you decide to participate, you would be free to withdraw from the study at any time. You should however first inform the doctor or specialist nurse involved with the study and return all devices. Such withdrawal will not in any way affect the standard of your future medical care and whether or not you participate, your doctors will give you the same standard of treatment.

If you have any problems at all during the study, please contact: Professor Linda Cardozo, Department of Urogynaecology, Telephone: 0171 737 4000.

References

[1]Abrams P., Blaivas J.G., Stanton S.L., Andersen J.T. The standardisation of terminology of lower urinary tract function. Br J Obstet Gynaecol 1990 97: (Suppi 6) 1-16.

[2] Swift S, Utrie J. The need for standardisation of the Valsalva leak point pressure. Int Urogynecol J. 1996;7:227-30.

[3] Swift S, Ostergard D. Evaluation of current urodynamic testing methods in the diagnosis of genuine stress incontinence. Obstet Gynecol 1995;86:85-91.

[4] Nidela F, Wall L. Stress incontinence diagnosed without multichannel urodynamic studies. Obstet Gynecol 1998;91(6):965-8.

CHAPTER SEVEN

OUTCOME MEASURES

INTRODUCTION

In making a choice of outcome measures it is essential to have an understanding of the principles of measurement with regard to GSI. Measurement consists of the application of a set of rules for assigning values to events so as to represent quantities or categories of attributes. The rules must be clear-cut, unambiguous and standardised, so that the same results will be obtained by different researchers using the same instruments. Each instrument should also measure what it is intended to measure. In selecting the appropriate outcome measures for this thesis, we were mindful of the need for measures with established reliability and validity, the problems of responsiveness as well as practical considerations and feasibility.

The use of health-related measures allows discrimination between individuals so that we can describe differences in health experience [1]. We require a measure which is capable of detecting GSI so that we can identify and target this group for the interventions. The outcome measures are used for the purpose of evaluation, focusing attention on changes between points A and B, which are attributable to the intervention of continence devices, utilising not only quantitative and qualitative changes but also those of health and quality of life. Within these broad categories we are interested in detecting differences in groups and not individuals and measuring the magnitude of these differences or outcomes. The level of precision required of the outcome measure will be determined by the expected magnitude of differences. To assess the efficacy of two continence devices may require a much more precise measure as the expected changes may be relatively small.

The outcome measures and methods of measurement are described in the thesis stating their objectives and intended purpose. The background and development are described, the method of scoring and scaling is summarised and available evidence on reliability and validity reviewed. Reproducibility data is provided or its absence indicated. Comments are also made on the ease or difficulty of administering the measure.

OUTCOME DATA
PRINCIPLES AND CHOICE OF MEASURE

The selection of an outcome variable depends on the nature of the interventions being studied. The end points were picked so that they best reflect the essence of the study. Outcome is to define and estimate the degree of reestablishment of function, complications, quality of life and morbidity related to device utilisation. No single measure can fully express the outcome of an intervention. The study includes not only the outcome as judged by the patient, but also as it is estimated by the clinician and possibly society. Because these are difficult to render precise one must acknowledge that there is a hazard that the measures selected will reflect primarily the objectives of the clinician. There is a large difference between the outcome for the patient and the outcome assessed by the patient. A woman with GSI may be made "dry" with a continence device and be satisfied with the result but she still considers herself incontinent.

The reliability of the methods and measurements used to assess the outcome of a study are vital to the scientific evaluation of that study so as to allow useful precise interpretation of the outcome [2]. The reliability of a test depends on the accuracy and reproducibility of the method of measurement. The diagnostic accuracy is determined by verifying test results against a reference standard that defines true disease status. A combination of outcome measures will enhance the overall significance and value of the study. The measure chosen should reflect the degree of change or improvement with a high degree of correlation. These will all clarify the strength of the various measures. The following definitions and terms were applied [3].

Accuracy: conforming to a standard or a true value (accuracy is distinguished from precision in this way: a measurement or statement can reflect or represent a true value without detail).

Precision: the quality of being sharply defined or stated through exact detail.

Reliability: the degree of stability exhibited when a measurement is repeated under identical conditions.

Validity: an expression of the degree to which a measurement measures what it purports to measure.

RESPONSIVENESS

It should also be recognised that the usual methods of establishing reliability and validity do not necessarily indicate how responsive an outcome measure is to change. Responsiveness to clinically significant changes in individuals over time is a major consideration in this study where the aim is to evaluate the impact of continence devices. Many measures used in the assessment of women with GSI are not suitable for intervention studies because of lack of standardisation, poor or unproven reliability and validity and failure to identify small but clinically significant changes attributable to the intervention. In this thesis, I have given a description of such measures and a critique of their application. I have also described some outcome measures used in trials of similar devices which at first were considered inherently useful but were excluded from use in the trial.

Scientific criteria are vital but practical considerations are likewise important. The choice of the best measure for a particular property will often be a compromise between scientific rigor and practical constraints. The administration of the measure is one example. It may be self administered by the patient or administered by the researcher. When administered by the researcher, there are certain advantages and disadvantages. There are constraints of time and resources, and the sample population may be restricted to a small geographic area. In general the response rate is higher than self-administered measures.

OUTCOME MEASURES IN LOWER URINARY TRACT DYSFUNCTION

We have the methods to measure QoL, direct observations made by the physician (PWT, MSU, urinary diary) and patient (subjective measures of comfort, ease of insertion, urinary leakage with device in situ). The woman may be satisfied with the device because the symptom of stress incontinence is reduced or "cured", but the clinician may be dissatisfied because the degree of PWT improvement was less than expected. Society at large may be content as the patient can go to work and the patient's relatives may be pleased because she can participate in common activities once more. The outcome of the trial will be described with measures from the following domains:

1. PATIENT'S OBSERVATIONS
2. CLINICIAN'S OBSERVATIONS
3. QUALITY OF LIFE AND IMPACT OF SYMPTOMS

All methods, definitions and units conform to the standards recommended by the International Continence Society, except where specifically noted [4].

DOMAIN OF PATIENT'S OBSERVATIONS

MEASUREMENT OF PATIENT OBSERVATIONS AND SYMPTOMS

Patient self-assessment is fundamental but as an outcome measure, patient derived symptoms response is insufficient on its own in diagnosing the aetiology of bladder dysfunction or response to intervention. We acknowledge that the accuracy of self-reported data is questionable and interpretation of clinical versus statistical significance is difficult. It is a common clinical experience that a stoical individual may cope well with symptoms of incontinence which in a more fastidious patient would prove intolerable. To help improve the quality of the data, the presence and degree of severity of urinary symptoms was assessed using the Kings Health urinary symptom questionnaire and will be described later.

FOREIGN BODY SENSATION

Women were asked to note whether or not they experienced any bothersome foreign body sensation with device use. Subjects were instructed to consider any unpleasant or uncomfortable sensation within the vagina as "irritating". They were also asked to note if it persisted for the duration of device use or if it wore off over the time of that single device use. They also noted any persistence of foreign body sensation after the device was removed.

EASE AND COMFORT OF DEVICE USE

Patient ratings on ease of placement and comfort of use, assessment of urine loss with specific activities and the overall protection afforded by device use were recorded at each follow-up visit.

Self-assessment of ease of placement of each device was graded via a five point scale. This also allowed comparison of patient experiences during use of devices.

- 1= Very easy to place device
- 2= Easy
- 3= Manageable
- 4= Difficult
- 5 = Very difficult

Self-assessment of the comfort of use of each device was graded via a five point scale.

- 1= Very comfortable
- 2= Comfortable
- 3= Mild discomfort
- 4= Uncomfortable
- 5 = Very uncomfortable

URINE LOSS WITH SPECIFIC ACTIVITIES

Self-assessment of urine loss before and after device insertion via a five point rating scale was used. This allowed comparison of patient experiences during various activities prior to and during use of the devices.

- 1= No urine loss
- 2= Slight urine loss
- 3= Mild urine loss
- 4= Moderate urine loss
- 5 = Severe urine loss.

ACTIVITIES RATED

Sitting/lying

Standing

Walking

Lifting/bending

Low impact exercise

High impact exercise

Cough/sneeze/laugh

ASSESSMENT OF OVERALL DEGREE OF DRYNESS

Women rated the overall degree of protection afforded (dryness) using a five point rating scale.

- 1= No urine loss
- 2= Slight
- 3= Mild urine loss
- 4= Moderate urine loss
- 5= Severe urine loss

DOMAIN OF CLINICIAN'S OBSERVATIONS

QUANTIFICATION OF URINE LOSS

To assess and compare the results of treatment of incontinence in different centres, the ICS Standardisation Committee has issued guidelines on tests to measure or quantify urine loss [4]. The number of incontinence episodes experienced per week, the number of continence pads used per week, both recorded on a urinary diary and the amount of fluid lost on a quantitative pad weight test are three standardised and validated measures of incontinence severity in women (Table 7.1)[5 6].

	Standardised measures of incontinence severity
1.	The number of incontinence episodes experienced per week recorded prospectively on a 5-day urinary diary.
2.	The number of continence pads used per week recorded prospectively on a 5 day urinary diary
3.	The amount of fluid lost on a quantitative pad test.

Table 7.1 Standardised and validated measures of incontinence severity in women.

URINARY DIARY

Symptoms such as the frequency of incontinence episodes are susceptible to error of recollection. It is thus of great importance to gain an objective assessment not only as an aid in deciding on the presence and severity of a problem but also on the results of its management. This would also be important in evaluating interventional therapies such as continence devices and for comparing results not only within the trial but also with other clinical trials of similar devices. The frequency/volume chart is one such objective measure and records the systematic registration in point of time of voiding and voided volume performed by the patient for a specified period of time. The chart can be supplemented with the registration of incontinence episodes. Measurements obtained from the frequency/volume chart include total voided volume per 24 hours, frequency of micturition, mean voided volumes, range of voided volumes and incontinence episodes. It is a simple and non-invasive method of documenting urine loss and has the potential to be reliable and sensitive to therapeutic interventions [7]. A 3 day diary indicating frequency of micturition, voided volumes and incontinence episodes is very helpful and even a 48 hour frequency volume chart has been shown to be a valuable and credible instrument for assessing micturition patterns in women [5] [8]. Urinary diaries have been shown to be a particularly reliable method for assessing the frequency of incontinence episodes and have been used successfully in studies of women with GSI [5]. Since the chart represents an objective account of the patient's history it carries by definition a high degree of internal validity. It is a recording of a real life event whereas a urodynamic investigation is an attempt to recreate a situation in a laboratory setting [9].

Wyman et al (1988) investigated the use of a one-week urinary diary in the evaluation of 50 community-dwelling incontinent women [5]. Diurnal micturition frequency, nocturnal frequency and number of incontinent episodes were highly reproducible and did not differ by urodynamic diagnosis. Test-retest correlation was highest with diurnal frequency and incontinence episodes. The value of routine registration of fluid intake would appear to be limited mostly to those with irritative urinary symptoms and in studying the results of treatment in patients with these symptoms of frequency, urgency and urge incontinence [9]. Registration of fluid intake on the follow-up diaries was not recorded in the study. The mere task of recording may of course increase the awareness of the bladder which could lead to modified

voiding behaviour. This approach relies on the ability and willingness of the subjects to comply with the study.

NORMAL VALUES

There are good data available on what should be considered a normal frequency/volume chart. Kassis and Schick (1998) established baseline data on normal asymptomatic women. They found that the functional bladder capacity was larger at night and voided volume tended to double the daytime volume. Nocturia was rarely seen and frequency was about 6 times per day. The mean total voided volume was 1473ml (± 386ml) and the ratio between night-time and daytime diuresis was 0.81 (± 0.3) [10]. The parameters of the urinary diary are summarised in table 7.2.

Parameters of the urinary diary

Parameters	**Daytime period**	**Night-time period**
Mean voided volume (ml)	237 (± 67)	379 (± 132)
Frequency	5.63 (± 1.26)	0.08 (± 0.16)
Diuresis (ml/min)	1.11 (± 0.35)	0.84 (± 0.27)
Time to next voiding (min)	222 (± 60)	454 (±50)
Total voided volume (ml)	1005 (± 497)	409 (±130)
Output per 24 hr (ml)	1473 (± 510)	
Diuresis ratio (night/day)	0.81 (± 0.30)	

Table 7.2 The parameters of the urinary diary. Mean (± Standard Deviation)

Normal values with reference to the frequency volume diary for a healthy female population as well as values for women with GSI and with urge incontinence have been documented by Larson and Victor (1988) [11]. Table 7.3 shows the median, 2.5 and 97.5 percentile of the measures of the frequency/volume chart.

Frequency / volume chart			
	Normal	Urge Incont.	Stress Incont.
Total voided vol (ml/24hrs)	1350	1490	1550
2.5 and 97.5 percentile	630-2580	630-2390	750-2800
Frequency of micturition/24hrs	5.5	9.5	6.5
2.5 and 97.5 percentile	3.5-9	5.5-14.0	4-10.5
Mean voided vol (ml)	240	170	220
2.5 and 97.5 percentile	120-430	70-270	110-430
Voided vol (ml)	350	250	400
2.5 and 97.5 percentile	140-950	70-650	180-790
Largest single voided vol (ml)	450	330	500
2.5 and 97.5 percentile	200-1000	150-700	200-850

Table 7.3 The median, 2.5 and 97.5 percentile of the measures of the frequency/volume chart. {Larson and Victor (1988)}.

It was a requirement of this trial that women completed a 5-day urinary diary for the week preceding their urodynamic investigations recording fluid intake, urine output, incontinence episodes and the number of pads used. At follow-up visits, similar diaries were kept but without measurement of voided volumes.

PAD WEIGHING TESTS

The health care attendants subjective assessment of "wetness" has been shown to be an extremely crude indicator of the degree of incontinence when compared to weight gains in pads in the same individual [12]. Difficulties with determining "wetness" can be overcome by weighing pads before and after specified time intervals. The pad-weighing test is one of the earliest, best known and most extensively used measure of the presence and severity of urinary incontinence in women and is reliable and reproducible [13 14 15]. The indications for a pad test are to quantify urine loss either before or after an intervention or treatment or to confirm incontinence in a woman who is not incontinent during a more formal urodynamic investigation. Objective assessment of the severity of stress incontinence by weighing perineal pads influences the type of treatment and can be used to monitor the response to treatment [16]. The PWT is designed for completion by an observer. It is easily performed and readily

applicable in a clinical situation. For these reasons it is well suited for use in routine clinical and research practice.

Pad tests fall into two broad categories, those that are carried out in hospital, laboratory or office and those that are conducted by the patient in the home or work environment [17].

The 24-hour home pad test has the advantages of being performed in familiar surroundings and can include known provocative situations which may be impossible to duplicate in a laboratory. However, studies suggest that the reproducibility of the test seems insufficiently satisfactory to allow its use in comparative scientific studies [18].

To standardise the pad test, the ICS introduced the one-hour pad-weighing test which measures the urine loss as weight gain of perineal pads under standard conditions [4]. The reproducibility is improved by having a standardised volume in the bladder but this does require catheterisation of the patient and adds to the invasive nature of the test [19]. Clear and unambiguous instructions also ensures high levels of reliability.

The amount of urine lost during the investigation is determined by weighing a collecting device such as a nappy or absorbent perineal pad. Immediately before the test begins the collecting device is weighed to the nearest 0.5 gram. The pad is worn inside the subjects underpants. Care is taken to use the correct size of pad in relation to the expected quantity of leakage based on the patient's guidance and the urodynamic test results. At the end of the one-hour test the collecting device is removed and reweighed. In interpreting the results weight increases of less than 1 gram can be due to perspiration, discharge and weighing error. If the collecting device becomes saturated during the test it is removed, weighed, and replaced by a fresh one.

The following is the typical test schedule for the ICS pad test as practised at KCH and used in the trial.

PAD WEIGHT TEST SCHEDULE

1. Patient voids to completion.
2. The patient is catheterised using an aseptic technique and the residual volume recorded.

3. The bladder is filled via the indwelling catheter with 250ml of normal saline using gravity fill. The catheter is then removed.
4. The pre-weighed pad is put on and the 1hr test begins.
5. The subject does not drink during the test.
6. Over a 30-minute period, the subject walks, including stair-climbing equivalent to one flight up and down.
7. During the remaining period, the subject performs the following activities
   - ⇨ standing up from sitting, 10 times
   - ⇨ coughing vigorously, 10 times
   - ⇨ star jumps for 1 minute
   - ⇨ bending to pick up a small object from floor, 5 times
   - ⇨ washing hands in running water for 1 minute.
8. At the end of the 1-hour test the pad is removed and weighed.
9. If the test is regarded as representative, the subject voids and the voided volume recorded.

Certain modifications to the PWT schedule are sometimes necessary. If the pad becomes saturated during the test, it is removed and weighed and replaced by another fresh pre-weighed one. The activity programme is modified according to the individual's physical ability. Any variations are noted so that the same level of activity is performed in subsequent visits for that individual subject.

Versi and Cardozo (1986) investigated the sensitivity of perineal pad testing and the videographic diagnosis of GSI in postmenopausal women [20]. They found that despite individual variations, the severity of GSI detected videographically was corroborated by the findings on pad testing. If the videographic diagnosis of GSI was accepted as the "Gold Standard" then the pad weighing test had a 14% false-negative rate, implying that videographic testing was more sensitive and probably more specific than pad tests in the diagnosis of GSI. However, the technique they used involved physiological filling of the bladder by drinking 500ml of water over 20 minutes prior to the 1-hour test. The test was not performed with a standard volume of urine in the bladder for all subjects. The 99% upper confidence limit for pad weight gains in 90 normal women was 1.4g. There was no statistical difference between the mean pad weight increase in young or postmenopausal women (0.33g Vs 0.40g respectively). The overall mean pad weight gain was 0.3g.

NORMAL PWT

Sutherst et al (1981) assessed 50 healthy women with normal urinary control and performed a 1-hour pad weight test so as to provide data to compare in women with GSI [16]. The mean PWT increase per hour was 0.26g (SD 0.36, range 0 – 2.1). The greatest weight increase in any 10 minute period averaged 0.15g (SD 0.17, range 0-0.8). It was thought that these small weight gains were due to perspiration or vaginal discharge. In 95% of women (mean + 2SD) the total weight gain was less than 1g over the whole hour and not more than 0.5g in any one pad.

Lose et al (1989) found that the 95% upper confidence limit was 8g over 24 hours, so it is reasonable to assume that the home pad test will result in a background loss of less than 1g every 3 hour of pad use [21].

Wall et al (1990) performed the ICS standardised PWT in 23 asymptomatic continent women. The maximum PWT gain was 0.7 g (mean 0.1g)

In a later study by Versi et al (1996) it was demonstrated that the mean PWT increase over 48 hours in continent women was 7.13g (SD 4.32) giving a 95% upper confidence level of less than 15g [22].

The findings of various authors on the pad weight test gains in normal women is depicted in table 7.4.

Pad weight test gains in normal women	
Study	**PWT gain (mean)**
Sutherst (1981)	0.26g (max 2.1g) per hour
Versi (1986)	0.3g per hour
Lose (1989)	8g per 24 hours
Wall (1990)	0.1g (max 0.7g) per hour
Versi (1996)	7.13g per 24 hours (SD 4.32)

Table 7.4 Illustration of the findings of various authors on the pad weight test gains in normal women.

MEASURES TO ASSESS URETHRAL FUNCTION

The correlation of urodynamic measures of urethral resistance with clinical measures of incontinence severity in women with pure genuine stress incontinence is not straightforward.

URETHRAL PRESSURE PROFILE

The urethral pressure and the urethral closure pressure are idealised concepts which represent the ability of the sphincter mechanism to prevent leakage. Urethral pressure measurement is a procedure used for assessment of the urethral sphincter function during storage. In current urodynamic practice the urethral pressure is measured by a number of different techniques which do not yield consistent values. Not only do the values differ with the method of measurement but also there is often lack of consistency for any single method [4].

Urethral pressure transmission ratios of less than or equal to 90% is considered a positive result [23]. If it occurs in any one third of the urethra it has limited discriminatory ability with a 54% sensitivity and 79% specificity. If it occurs throughout the length of the urethra this is more specific (93%) but has such a poor sensitivity (22%) that it is of little clinical use in detecting GSI.

The techniques available are subject to pitfalls in interpretation and test-retest variation. The UPP parameters do not 1) discriminate stress incontinence from other disorders, 2) provide a measure of the severity of the condition and 3) return to normal after successful incontinence surgery. It is however helpful in demonstrating a low pressure urethra which may have therapeutic implications [24 25].

PRESSURE TRANSMISSION RATIOS

The correlation between the degree of urethro-vesical junction mobility and the urethral pressure transmission ratio (PTR) is not a reliable predictor of increased bladder neck mobility [26]. It is widely accepted that pressure transmission ratios are subject to marked variation and the overlap in values between normal and women with GSI is so great that the PTR cannot be regarded as a valid method of predicting whether the urethral closure mechanism is competent or not to start with [27 28]. Hence it can not be reliably used to detect any change in the continence mechanism or urethral function as a result of using one or other of the devices for the period of the study.

VALSALVA LEAK POINT PRESSURE

The Valsalva leak point pressure (VLPP) is a recently introduced urodynamic study that was described by McGuire et al (1993) as the measure of the total abdominal pressure to initiate urinary leakage demonstrated on VCU with the subject in the upright position with a 10F catheter in situ and 150ml in the bladder [29]. It has rapidly gained favour in the investigation of adult female urinary incontinence. It is currently being endorsed as a severity measure for dysfunction of the continence mechanism and for evaluating women with GSI and to diagnose the condition termed intrinsic sphincter deficiency (ISD). The values attained in urodynamic testing are being advocated for use in clinical trials despite a relative lack of outcome data.

Multiple parameters have been shown to affect the VLPP: catheter calibre, catheter location (vaginal versus intra vesical), bladder volume, the use of coughing versus Valsalva as the provocative manoeuvre, patient position and the use of absolute or a change in measured pressure [30]. But most importantly, there is no agreement on how to perform the test. Until a standardised validated technique is defined and accepted, investigators will not be able to compare data in clinical trials or make recommendations regarding patient management [31].

In summary, UPP, PTR and Valsalva LPP measurements are unnecessary to make the diagnosis of GSI or quantify urine loss according to the criteria of the ICS. Dynamic UPP variables have no correlation with the severity of urethral sphincter dysfunction. In addition it is not known whether UPP or Valsalva LPP are valid measures of urethral sphincter dysfunction in women with anterior vaginal wall prolapse of varying degrees since pelvic organ prolapse can affect both active and passive measures of urethral resistance. Hence we felt that the stress UPP and the VLPP could not be used as baseline and outcome measures to assess urethral sphincter function prior to and following the interventions used in the study. For these reasons the pad weight test gains without the device in situ at the completion of the study were compared to the baseline test results and used as a measure of change in urethral function as a consequence of device use over time.

DOMAIN OF QUALITY OF LIFE MEASUREMENTS AND IMPACT OF SYMPTOMS

HEALTH STATUS PROFILES

Regardless of how it is derived, an index of health should have certain desirable properties:

- Reliability validity and sensitivity to change
- Consists of clearly defined component parts
- Each question makes an independent contribution to the event measured
- Scoring and interpretation is simple and meaningful

Two measurement approaches are commonly used to assess health-related quality of life (HRQL): generic and condition-specific. Generic HRQL instruments are designed to be used across multiple disease states or conditions and gender norms. These may include instruments that measure only a single area of HRQL or those that measure multiple areas. Generic measures are designed for general applicability rather than specifically for a single condition. Instruments able to measure single or multiple HRQL areas are available, however, few of these have been tested for reliability and sensitivity in incontinent female populations. Results from generic measures can of course be compared with data from other populations and illness groups. For example, normative data can be used to compare health status data from a particular patient group with that of the general population [32].

Where generic measures are insufficiently responsive to clinically significant change, a disease specific measure is necessary which is designed to measure the impact of a particular condition. or are used to detect the effect of intervention. These instruments tend to be more responsive than generic instruments in detecting treatment effects. Generally, the symptom scales include measurement of the presence of a symptom as well as the "bothersome" or "troublesome" nature of it. It is however still important that disease specific measures are used alongside the generic measures to elucidate certain aspects of ill health that are unique to particular illnesses. Questionnaires are often developed and used in studies without prior piloting and validation or previously validated instruments are used inappropriately

without due consideration for the sensitivity required of the instrument or its applicability to the study population [33].

THE UK SHORT FORM 36
HEALTH SURVEY QUESTIONNAIRE (SF-36)

The SF-36 is a health status questionnaire developed as a result of two large scale American studies. The first, the Rand Health Insurance Experiment (RHIE), was a research project to determine the best possible methods for measuring a broad array of functioning and health status concepts and to compare the outcomes of different methods of delivering care [34]. The Medical Outcomes Study (MOS) developed and refined these measures further and was a large scale test of the feasibility of self-administered questionnaires and generic scales to assess the outcome of medical care [35].

Description of the SF-36

The SF-36 is a short questionnaire with 36 items which measure eight variables (Table 7.5). There is a further unscaled single item on changes in respondent's health over the past year. This item was not analysed for the purpose of this thesis as follow-up was performed six months following treatment and rewording the questionnaire was not appropriate.

Dimensions of the Short Form 36
• Physical function (10)
• Social function (2)
• Role limitation due to physical problems (4)
• Role limitation due to emotional problems (4)
• General mental health (5)
• Energy / vitality (4)
• Bodily pain (2)
• General health perceptions (5)

Table 7.5 Dimensions of the Short Form 36 (Numbers in brackets refer to the number of questions in each dimension).

Scores on each of the dimensions are obtained by summing item responses and with the use of a scoring algorithm, transforming these raw scores into a scale from 0

(worst possible health state) to 100 (best possible health state). By this method each of the individual domains which contain a different number of items are scored out of the same total and can therefore be compared with one another. The developers suggest that the SF-36 should take respondents approximately 5 to 10 minutes to complete. Evidence from studies in the United Kingdom suggest that respondents find it easy to complete and response rates in postal surveys using the questionnaire are high [36].

VALIDATION, RELIABILITY TESTING AND NORMATIVE VALUES

Two recent British studies have confirmed the reliability and validity of the SF-36 and provided normative data. The first, 'The Oxford health life survey', was a postal survey in which the SF-36 and questions on lifestyle, demographics and medical health were sent to 13,042 randomly selected subjects aged 18 to 64 years residing in Bershire, Buckinghamshire, Northamtonshire and Oxfordshire. The response rate to questioning was 72%. The internal consistency of the variables in the SF-36 was assessed with the Chronback's alpha statistic and results are shown in table 7.6.

Internal consistency testing of the SF-36	
Dimension	**Chronback's Alpha**
Physical function	0.90
Social function	0.76
Role limitation due to physical problems	0.88
Role limitation due to emotional problems	0.80
General mental health	0.83
Energy / vitality	0.85
Bodily pain	0.82
General health perceptions	0.80

Table 7.6 The internal consistency testing of the SF-36. (Jenkinson et al 1993)

Garrett et al (1993) used the SF-36 to evaluate four different medical conditions. 1,787 patients aged 16 to 86 were selected from four large group general practices in the Grampian area. All of the patients had either low back pain, menorrhagia, suspected peptic ulcer or varicose veins. A random sample of 900 members of the general population, selected from the electoral register for Aberdeen served as a

comparison group. The response rate to questioning was 75.5% from the patient group and non-responders were significantly younger than responders. 60.2% of the control group completed the questionnaire. Chronback's alpha coefficients for all eight scales of the questionnaire exceeded 0.8 satisfying the criteria for internal consistency testing. Validity testing confirmed that modifying the questionnaire to make it suitable for the British public had not altered its validity. The designers of the questionnaire suggest that where normative data sets exist these can be used for comparison purposes with other populations and samples and this was performed in this thesis.

ADVANTAGES AND LIMITATIONS OF THE UK SF-36

The SF-36 is short, acceptable to patients and covers a wide range of areas that may be adversely affected by health. The questionnaire has the potential advantage that it may be more sensitive to lower levels of dysfunction and disability. Scoring is by a discrete adjectival as opposed to a dichotomous scale which may explain its greater sensitivity. Population norms are available for use in the UK and are published in the SF-36 users manual.

DISEASE SPECIFIC QUALITY OF LIFE ASSESSMENT

KINGS HEALTH QUESTIONNAIRE

The Kings Health Questionnaire (KHQ) was developed and validated as a condition-specific instrument to measure and objectively evaluate the quality of life and impact of symptoms of women with urinary incontinence [37]. It has also been used as a predictor of the course of incontinence, needs of care and functional outcome of women with GSI. The intention of the authors was to acquire a measure which could be used in both research and clinical practice to judge the efficacy of different interventions in the management of urinary incontinence. The questionnaire is intended for use alongside a generic questionnaire such as the SF36. By using both questionnaires simultaneously the QoL of women with urinary problems can be compared to that of women with other conditions whilst retaining the additional sensitivity of the specific measure for intervention studies.

The KHQ is designed to be self-administered by the patient and should be completed in approximately 10 minutes by most women. It is also designed for postal survey. There are 21 questions presented in eight different domains, with a separate scale for measurement of the severity of urinary symptoms. A four-point scoring system is used for each of the items, and includes an inapplicable option to enable all respondents to answer each item of the questionnaire. This system allows each of the domains to be scored out of the same total and therefore each contributes similarly to the overall questionnaire score. Scores in each domain range between zero and 100, a higher score indicating a greater impairment of quality of life. The KHQ is designed for the assessment of urinary incontinent women and therefore the domains of incontinence impact, urinary symptoms and incontinence severity measures are not found in the SF36. In addition, sleep disturbance and sexual impairment are both major determinants of the QoL impairment of urinary incontinent women and both are included in the KHQ. Unfortunately no questions relating to these aspects of the QoL of respondents are included in the SF36 which is a major criticism of the value of the SF36 used to assess urinary incontinent women. Despite these differences there are domains common to both questionnaires and these are shown below (Table 7.7).

Domains common to both questionnaires		
Domain	**UK SF-36**	**KHQ**
General Health	•	•
Incontinence Impact	**NA**	•
Urinary symptoms	**NA**	•
Incontinence severity measures	**NA**	•
Changes in health	•	**NA**
Physical function	•	•
Role limitations	•	•
Social limitations	•	•
Emotional problems	•	•
Energy / vitality	•	•

Table 7.7 Domains common to the SF-36 & KHQ.

RELIABILITY AND VALIDITY

Internal consistency was measured using Chronbach's alpha statistic [38]. An alpha value of 0.7 or more is thought to be acceptable. Internal consistency exceeded this requirement in all domains (Table 7.8). The reliability of the questionnaire was excellent in terms of its internal consistency and its test-retest reliability.

Domain of KHQ	Internal consistency	Test	Retest scores	Rho
Limitations			Mean (SD)	
Role	0.785	Test 1 Test 2	35.89(29.41) 37.84(27.33)	0.94
Physical	0.725	Test 1 Test 2	42.79(28.92) 44.29(28.20)	0.96
Social	0.785	Test 1 Test 2	20.32(22.65) 22.87(21.57)	0.80
Personal	0.892	Test 1 Test 2	10.51(14.72) 12.61(15.27)	0.87
Emotional problems	0.876	Test 1 Test 2	37.34(28.30) 39.16(26.64)	0.92
Sleep/energy upset	0.784	Test 1 Test 2	46.40(26.05) 48.10(25.30)	0.88
Severity measures	0.778	Test 1 Test 2	44.44(28.77) 47.00(25.62)	0.94

Table 7.8 Internal consistency (Chronbach's alpha statistic) and test-retest reliability scores for the KHQ (Spearman's rho non-parametric correlation coefficients).

CRITERION VALIDITY TESTING

The criterion validity of the KHQ was confirmed against the UK SF-36. Spearman's correlation coefficients were used to compare the results of the KHQ and the SF-36 in the common domains (table 7.9) [37]. There was a significant correlation between the common domain scores for both questionnaires.

Correlation coefficients between domain scores on the SF-36 and KHQ	
Domain	**Spearman's correlation {R (Significance)}**
General health	-0.648 ($p<0.001$)
Incontinence Impact	NA
Urinary symptoms	NA
Incontinence severity measures	NA
Changes in health	NA
Physical function	-0.342 ($p < 0.01$)
Role limitations	-0.461 ($p < 0.005$)
Social limitations	-0.512 ($p < 0.001$)
Emotional problems	-0.465 ($p < 0.001$)
Mental health	NA
Energy / vitality	-0.617 ($p < 0.001$)

Table 7.9 Domains covered by the Kings Health Questionnaire and the UK Short Form 36 health survey questionnaire applicable to urinary incontinent women.

(Correlation coefficients (Spearman's) between domain scores on the two questionnaires). (Kelleher et al 1996)

CONCLUSION

Health is more than the absence of disease and its negative consequences and much emphasis has been placed on the quality of life of the individual and positive health. The concept of positive health has important implications for attempts at measurement. Outcome measures must incorporate ways of assessing the subjective experiences of the individual while using a particular device. We can measure patient satisfaction with the intervention in terms of the individual's own particular frame of reference or against universal criteria. The measures developed for the KHQ have been thoroughly tested for reliability and validity. Initial validation studies of the KHQ have shown that it possesses the basic psychometric properties required of a condition specific questionnaire for the assessment of women with urinary incontinence. Women who completed the King's Health Questionnaire also completed the UK Short Form 36 health survey questionnaire. This questionnaire was chosen as it is the most recently developed of the accepted generic quality of life measures. In addition the questionnaire is presented in the same manner as the KHQ. The major difference between the two questionnaires is that high scores on the KHQ represent a poorer QoL whereas higher scores on the SF36 indicate a better QoL.

The aim of the follow up phase of the thesis was to present the same questionnaires completed at enrolment into the study at a suitable interval following treatment with the continence devices. In order to allow follow up of a large group of women, an interval of six months following the commencement of therapy was chosen as a reasonable time over which to detect some change in QoL.

References

[1] Kirshner B, Guyath G. A methodological framework for assessing health indices. J Chr Dis, 1985;38:27-36.

[2] Urinary Incontinence in Adults. Clinical practice, Guidelines. No 2 Update. Us Department of Health and Human Services, Public Health Service. Agency for Health Care Policy and Research (AHCPR). Publication No 96, 0682, December 1995

[3] Drummond MF, Stoddard GL, Torrance GW: Methods for the Economic Evaluation of Health Care Programmes. Oxford University Press, Oxford 1987
Last John M: A dictionary of epidemiology. Oxford University Press, New York, Oxford, Toronto 1988

[4] Abrams P., Blaivas J.G., Stanton S.L., Andersen J.T. The standardisation of terminology of lower urinary tract function. Br J Obstet Gynaecol 1990 97: (Suppi 6) 1-16.

[5] Wyman J, Choi S, Harkins S, Wilson M, Fantl J. The urinary diary in evaluation of incontinent women : a test – retest analysis. Obstet Gynecol 1988;71(6pt 1):812-17

[6] Fantle, J, Harkins S, Wyman J, Choi S, Taylor J. Fluid loss quantitation test in women with urinary incontinence: a test-retest analysis. Obstet Gynecol 1987;70:739-43.

[7] Larson G, Victor A. The frequency / volume chart in genuine stress incontinent women. Neurourol Urodynam 1992;11:23-31.

[8] Larsson G, Victor A. Micturition patterns in a healthy female population, studied with a frequency / volume chart. Scand J Urol Nephrol Suppl 1988;114:53-7.

[9] Siltberg H, Larsson G, Victor A. Frequency/volume chart: the basic tool for investigating urinary symptoms. Acta Obstet Gynecol Scand 1997;Suppl 166:76:24-27.

[10] Kassis A, Schick E. Frequency-volume chart pattern in a health female population. Br J Urol 1998;72:708-10

[11] Larsson G, Victor A. Micturition patterns in a healthy female population, studies with a frequency/volume chart. Scand J Urol Nephrol 1988;Suppl 114:53-7.

[12] Walsh J, Mills G. Measurement of urinary loss in elderly incontinent patients. Lancet 1981;I:1130-1132.

[13] Victor A. Pad weighing tests – a simple method to quantitate urinary incontinence. Am Med 1990;22:443-7.

[14] Klarskov P, Hald T. Reproducibility and reliability of urinary incontinence assessment with a 60 minute test. Proc Int Cont Soc 1983;13:512-14.

[15] Mood P, Murray A, Brown M, Sutherst J. Reproducibility of a one hour urine loss test (Pad test). Proc. Int Cont Soc 1983;13:515-17.

[16] Sutherst J, Brown M, Shaver M. Assessment of the severity of urinary incontinence in women by weighing perineal pads. Lancet 1981;1128-30.

[17] Mouritsen L, Berild G, Hertz J. Comparison of different methods for quantification of urinary leakage in incontinent women. Neurourol Urodyn 1989;8:579-587.

[18] Lose G, Jorgensen L, Thunedborg P. 24 Hour home pad weighing test versus 1 hour ward test in the assessment of mild stress incontinence. Acta Obstet Gynecol Scand. 1989;68:211-215.

[19] Lose G, Rosenkilde P, Gammelgaard J, Schroeder T. Pad weighing test performed with s standardised bladder volume. Urology 1988;32:78-80.

[20] Versi E, Cardozo LD. Perineal pad weighing versus videographic analysis in genuine stress incontinence. Br J Obstet Gynecol 1986;83:364-66.

[21] Lose G, Jergensen L, Thumedbory P. 24 hour home pad weighing test versus 1 hour ward test in the assessment of mild stress incontinence. Acta Obstet Gynecol Scand. 1989;68:211-215.

[22] Versi E, Orrego G, Hardy E, Seddon G, Smith P, Anaud D. Evaluation of the home pad test in the investigation of female urinary incontinence. Br J Obstet Gynecol 1996;103:162-167.

[23] Bump R, Copeland W, Hurt W, Fantl J. Dynamic urethral pressure/profilometry pressure transmission ratio determinations in stress incontinent subjects. Am J Obstet Gynecol 1988;159:749-55.

[24] Lose G. Urethral pressure measurement. Acta Obstet Gynecol Scand – Suppl 1997;166:39-42.

[25] Meyer S, DeGrandi P, Schmidt N, Sanzeni W, Spinosa J. Urodynamic parameters in patients with slight and severe genuine stress incontinence: is the stress profile useful? Neurourol Urodyn 1994;13(1)21-8.

[26] Meyer S, De Grandi P, Caccia G, Gerber S. Pressure transmission ratio: is it a reliable parameter in increased urethro-vesical function mobility? Neurourol Urodynam 1997;16(4):277-84.

[27] Versi E, Cardozo L, Cooper. Urethral pressures : analysis of transmission pressure ratios. Br J Urol 1991;68:266-70

[28] Lose G, Thind P, Colstrup H. The value of pressure transmission ratio in the diagnosis of stress incontinence. Neurol Urodyn 1990;9:323-4.

[29] McGuire E, Fitzpatrick C, Wan J, Bloom D, Sanvordenker J, Rithcey M, Gormely E. Clinical assessment of urethral sphincter function. J Urol 1993;150:1452-1454.

[30] Swift S, Ostergard D. A comparison of stress leak-point pressure and maximal urethral closure pressure in patients with genuine stress incontinence. Obstet Gynecol, 1995. 85 (5 pt 1): 704-8.

[31] Bump R, Elser D, Theofrastous J, McClish D, Continence Program for Women Research Group. Valsalva leak point pressures in women with genuine stress incontinence: reproducibility, effect of catheter calibre and correlation with other measures of urethral resistance. Am J Obstet Gynecol 1995;173:551-7.

[32] Jenkinson C, Coulter A, Wright L. Short form 36 (UK SF-36) health survey questionnaire. Normative data adults of working age. Br Med J, 1993. 306: 1437-1440.

[33]Gill T.M, Feinstein A.R. A critical appraisal of the quality of quality of life measurements. JAMA, 1994. 272: (8) 619-626.

[34]Stewart A. L., Ware J. E. Measuring functioning and well being: the Medical Outcomes study approach. London, Duke University Press, 1992.

[35]Ware J.E, Sherbourne C. The MOS 36 item short form health survey 1. conceptual framework and item selection. Medical Care, 1992. 30: 473-483.

[36]Brazier J. E, Harper R., Jones N. M. B., O'Cathain A., Thomas K.J., Usherwood T., Westlake. Validating the SF-36 health survey questionnaire: a new outcome measure for primary care. Br Med J 1992. 305: 160-4.

[37] Kelleher C, Cardozo L, Khullar V, Salvatore S. Anew questionnaire to assess the quality of life of urinary incontinent women. Br J Obstet Gynaecol 1997, 104; 1374-1379.

[38] Chronbach LJ, Meele P. Construct validity in psychological tests. Psychol Bull 1955;52:281-302.

CHAPTER EIGHT

MEASURES OF THE CONSEQUENCES OF TREATMENT

Evaluation of the treatment of stress incontinence with devices necessitates an assessment of effect. The outcomes against which success or failure are measured have traditionally been defined in terms of the presence or absence of disease. The medical model views disease within the following framework:
Aetiology – Pathology – Manifestations.

The test of continence devices is to eliminate the manifestations of urethral sphincter incompetence, namely the symptom of stress incontinence, through preventative means. While one is setting about obtaining a cure, it should be possible to alleviate the impact of the disease. It is not a treatment for the underlying conditions in which case our intervention would be measured in terms of a simple dichotomy, the presence or absence of ailment. But outcome needs to be defined as more than the lack of the manifestations of disease and must include other measures of the health of the individual patient. It is useful to think in terms of the consequences of GSI. Any two women suffering from stress incontinence will have widely differing needs because of the particular manifestations of the disease and its severity at a point in time.

Over the years, a variety of terms have been developed to provide a framework for describing the consequences of disease. The World Health Organisation (WHO) International Classification of Impairments, Disabilities and Handicaps is useful as it provides a clear distinction between the consequences of disease at three different levels; the continence mechanism, the individuals performance and the response of society (Table 8.1). Firstly, something abnormal occurs within the individual giving rise to urinary dysfunction (pathology) which then becomes evident. The pathological state becomes exteriorised and the woman is aware she is unhealthy because of the symptoms of incontinence. This heralds the recognition of impairment. Next, alterations in performance or behaviour of the individual result and represent the consequences of impairment and are termed disability. Finally, impairment or disability may place the woman at a disadvantage compared to others in society. This experience of disadvantage represents handicap [1].

WHO concept of consequence of disease or disorder			
Disease or Disorder	Impairment	Disability	Handicap
Intrinsic Situation	Experience exteriorised	Experience objectified	Experience socialised

Table 8.1 The WHO International Classification of Impairments, Disabilities and Handicaps.

This concept provides a useful and comprehensive framework not only for classifying the consequences of GSI for the individual, but also for evaluating the effects of our intervention, namely continence devices.

FACTORS TO CONSIDER FOR OUTCOME STUDIES IN PATIENTS WITH LOWER URINARY TRACT DYSFUNCTION.

GRADING OUTCOME

Bo et al compare the effect of pelvic floor exercises, electrical stimulation, vaginal cones, and no treatment for genuine stress incontinence [2]. The main outcome measures included the following: Maximum closure pressure, Pelvic floor muscle strength, Episodes of leakage in 3 days, Stress pad test (g), 24 h pad test (g), Leakage index and Social activity index. After 6 months there was no difference in the outcome measures of the women in the untreated group. This is a very good study demonstrating the natural history of genuine stress incontinence in women over a six month period.

Elimination of the symptom of stress incontinence is the goal of treatment and this comprises the expected outcome. A responder may be characterised by a response in the direction towards the normal and of a size exceeding the value of the test-retest variations. The definition of cure and normalisation is difficult in this study because the intervention is directed against symptoms and not against the underlying defect in the continence mechanism, so we can never expect to heal. The woman who uses a continence device might experience normalisation but the structural and functional defects remains: the PWT are the same or worse after 6 months. It may be better to evaluate continence devices in terms of the degree of improvement of symptoms (Table 8.2).

Evaluation of the outcome of The use of continence devices
- Cure
- Normalisation
- Degrees of improvement
- Responders or non-responders

Table 8.2 Factors to consider in the evaluation of the outcome.

It is impossible to accurately measure or even be aware of all potentially confounding variables when examining the relationship between the use of continence devices and the outcomes of that intervention. In order to measure and compare the benefits and risks of various continence devices one may utilise a number of approaches. The efficacy of the devices can be assessed against the standards set by other conservative and surgical methods of management already available. The following are measures of efficacy and treatment effect which were applied to the results of the study (table 8.3).

Measures of efficacy and treatment effect
1. Relative risk reduction
2. Absolute risk reduction
3. Number needed to be treated

Table 8.3 The measures of efficacy and treatment effect used in the trial.

RELATIVE RISK REDUCTION

Relative risk reduction is the reduction of adverse events achieved by a treatment, expressed as a proportion of the control rate. It is the difference in event rates between the control and treatment groups, divided by the event rate in the control group. One disadvantage of this measure of efficacy is that it does not reflect the magnitude of the risk without therapy. It will therefore overestimate or underestimate the absolute impact of therapy when adverse events in untreated patients are very rare or very uncommon respectively. Incontinence before use of a device was very common, so its clinical usefulness as a measure of efficacy suffers somewhat.

ABSOLUTE RISK REDUCTION

The absolute risk reduction or attributable risk reduction is the difference in event rates between the control (pre-treatment) and treatment groups. The advantage over the relative risk reduction is that it is an expression of the consequences of giving no treatment and therefore provides an additional measure of clinical effect.

NUMBER NEEDED TO BE TREATED

The "number needed to be treated" is the number of patients who must be treated in order to prevent one adverse event. Mathematically, this is equivalent to the reciprocal of the absolute risk reduction. It expresses efficacy in a manner that incorporates both the baseline risk without therapy and the risk reduction with therapy. It illustrates how much effort must be expended to prevent one event.

The relative risk reduction, the absolute risk reduction and numbers needed to be treated were calculated for each of the outcome measures Two or more incontinence episodes per day (IEPD), three or more continence pads used per 5 days and two or more grams lost on a one hour PWT were chosen as rates of adverse events signifying significant urinary incontinence.

MISSING DATA

The problem of missing data in clinical research trials is by no means a trivial one. Missing data are often described as either "dropout" or "intermittent". Dropout occurs when a subject, once missing an assessment, is never observed again. Intermittent missing data occurs when a subject misses an assessment but is later observed. While we are limited to the observed data, there is information to be gained from it which may give an insight to the mechanism giving rise to drop outs. For example, subjects who have worse QoL may be more likely to miss assessments but this is debatable[3]. The possible mechanisms for "dropouts" tested is given in table 8.4.

Possible mechanism giving rise to drop outs
Background characteristics
Mean age
Menopausal status
Premenopausal
Post menopausal
Use of HRT
Foreign body sensation
Ease and comfort of use of the device
Urine loss with specific activities
Overall degree of control of "wetness"
Quality of life disruption assessed by questionnaires
Mean number of IEPD
Mean number of incontinence pads used per 5 days
Severity of GSI
Moderate
Severe
Mean PWT gain – baseline
Measures of urinary leakage assessed at one month
SF36
KHQ

Table 8.4 Data which may offer an insight to the mechanism giving rise to drop outs.

STATISTICAL METHODS

Data were stored on computer and a statistician was consulted for advice and recommendations in the application of tests and statistical analysis. Analysis was assisted using SPSS for Windows statistical package. Data are presented as the mean (sd) and median values unless otherwise specified. To determine the correlation between variables, the non-parametric Spearman's rank correlation statistic was used. The level of significance employed in this thesis was the 5% level ($p<0.05$). Discrete variables were expressed as counts or percentages; continuous data as means with standard deviations, with calculation of 95% confidence intervals to measure the significance of differences. We analysed data according to the intention-to-treat principle.

POWER CALCULATION

A power calculation was performed and set a sample size of 50 in each group of the trial would be sufficient to show a difference between groups of 10% in each outcome measure at 6 months with power 90% and $p<0.05$.

Comparison of paired means.

In a case-control study such as this where the patient acts as her own control, comparisons are made of paired or individually matched samples. Every individual in one group (baseline) has a unique match in the other (device user) group. There is self-pairing – where the same individual belongs to both comparison groups. The approach to hypothesis testing in this paired situation is to take advantage of this situation. If, under the null hypothesis, the means of the two populations (before and after intervention) are the same, then the mean of the differences calculated on a sample of pairs of individuals should be close to zero. For such comparisons, the parametric paired *t* test was used for testing the two samples and the sample means [4].
The appropriate test statistic for the paired situation is given by

$t = [d - 0] / sd \div \sqrt{n}$ on n-1 degrees of freedom.

d = The observed mean of the differences

sd = The standard deviation of the differences

n = The number of pairs in the study

The 95% confidence interval for the mean difference between the two populations are calculated from

$d \pm t_c \times [sd / \sqrt{n}]$

$sd / \sqrt{n}$ = The standard error of the mean difference

t_c = is the two-sided 5% critical value for the *t* distribution.

Certain assumptions were made: - a) that the distribution of the variable is not markedly skewed in either of the two populations; b) the population variances were unequal; and c) the sample size in both groups combined was greater than 60 with numbers in each group roughly the same.

When performing statistical analysis of results obtained from two independent samples such as the urine loss on PWTs between groups, the ICS Standardisation Committee has suggested that non-parametric statistics should be employed, since the

values are not normally distributed. The Wilcoxon signed rank sum test was used to assess the differences between the results obtained in each group of device users.

COMPARABLE GROUPS

The main features of this intervention design are the aim of producing two groups of women with GSI comparable in respect of features known to affect outcome, except for the different interventions (Reliance or FemAssist) which it is planned they will receive. Women in each group were matched for characteristics like age, menopausal status and HRT, as well as the quality of life scores with the purpose of eliminating such characteristics from the analysis of efficacy of each intervention. The two groups were evaluated to check that there was a good "case-mix" so analysis was made of the comparability of the groups with respect to the baseline severity of incontinence as assessed by the PWT gains and the number of incontinence episodes per day and the number of pads used per five days recorded in the urinary diary. Statistical analysis was performed using the Wilcoxon signed rank sun test.

ASSESSMENT OF SUBJECTIVE DEGREE OF DRYNESS

The response to treatment while performing specific activities and the overall degree of protection afforded by each device as rated by the patients were categorised as "Completely Dry", "Significant improvement", "No better" or "Worse". The responses were defined as follows:

A) "Completely Dry" with device use was computed as 1 (scale 1 to 5)

B) "Significant improvement" was defined as >50% reduction in rating of urine loss during insert use (scale 1 to 5) compared with before insert use.

C) "No better" was defined as no statistically significant change in the rating.

D) "Worse" was defined as a statistically significant change in the rating in a less favourable direction.

ANALYSIS OF THE URINARY DIARY VARIABLES

Analysis was also performed for the baseline and one, three and six months post treatment urinary diary variables.

INCONTINENCE EPISODES PER DAY

Assessment was made of whether or not there was any difference in the degree of protection afforded by each device as judged by the number of incontinence episodes per day (IEPD) on the urinary diary at baseline without a device and after one, three and six months while using the particular device.

Individual patient responses on the urinary diary were categorised as follows:

1. "Dry" = no IEPD
2. "Significantly improved" = 75% reduction in IEPD
3. "Moderately improved" = 50% to 74% reduction in IEPD
4. "Slightly improved" = 25% to 49% reduction in IEPD
5. "No change" = ± 25% change from baseline
6. "Worse" = greater than 25% increase in IEPD].

INCONTINENCE PADS USED OVER 5 DAYS

Similar comparisons were made of the mean number of incontinence pads used over 5 days while using a device at the one, three and six months visit assessments with that obtained at study inclusion. This helped to assess if there was any difference in the degree of protection afforded by each device. Individual patient responses on the urinary diary were categorised as follows:

1. "Completely dry" = No pads used over 5 days of recordings
2. "Significantly improved" = 50% reduction in pad usage
3. "No change" = ± 25% increase change from baseline
4. "Worse" = greater than 25% increase from baseline pad usage

PAD WEIGHT TESTS

Comparisons were made, for each device group, of the PWT gains at baseline and at one, three and six months of device use. Using these methods we could then

determine if there were any statistically and clinically significant differences in the mean PWT gains at each visit as a consequence of device use. Individual patient responses were categorised as follows:

1. "Completely dry" – 1g of urine or less on PWT gains (the error limit of the measuring scale is ± 0.2g)
2. "Significantly improved" – less than 2g in urine loss but not completely dry
3. "Moderately improved" – between 2.1g and 3g in urine loss
4. "Slightly improved" – between 3.1g and 4.9g in urine loss
5. "No change" - 5g or more in urine loss
6. "Worse" – greater than 25% increase from baseline PWT gains.

URETHRAL FUNCTION

Assessment of urethral function as a result of device use was based on PWT gains at the start and end of the trial. The PWT data were compared using the parametric t-test evaluating the difference in PWT gains at baseline and at the 6-month visit when the test was performed without a device in place. This analysis was performed for each group.

ANALYSIS OF QUALITY OF LIFE

Analysis was performed for the baseline and six months post treatment quality of life variables for each group of device users. The two groups, Reliance users and FemAssist users were also compared using the non-parametric Wilcoxon signed rank test. In adopting generic and condition-specific instruments, it is recommended to compare results obtained in the study population with published norms. I wished to assess whether there was any disruption to the general health of women with GSI in

this study and how this might compare to the poorer quality of life experienced by women with other medical complaints.

Two published data sets have been incorporated into this study to allow these comparisons, a) The Oxford healthy life survey [5] and b) the study by Garratt et al (1993) [6]. The data from these two studies were used to compare the SF36 results of women in this study with those of the general population and those of women with other medical complaints. Analysis and interpretation based on minimum difference which is important to patient was also considered.

References

[1] World Health Organisation International Classification of Impairments, Disabilities and Handicaps. World Health Organisation, Geneva 1980.

[2] Bø H, Talseth T Holme I. Single blind, randomised controlled trial of pelvic floor exercises, electrical stimulation, vaginal cones, and no treatment in management of genuine stress incontinence in women. *BMJ* 1999;318:487-493 (20 February)

[3] Curran D, Bacchi M, Hsu S, Molenberghs G, Sylvester R. Identifying the types of missing data in quality of life data from clinical trials. Stats in Med 1998;17:739-756.

[4] Interpretation and use of medical statistics. Daly L, Bourke J, McGilvray J. Confidence intervals and hypothesis testing: two group comparisons. 4th edition Blackwell scientific publications. 1991

[5] Jenkinson C, Coulter A, Wright L. Short form 36 (SF-36) health survey questionnaire: normative data for adults of working age. BMJ 1993 306: 1437-1440.

[6] Garratt A, Ruta D, Abdalla M, Buckingham J, Russell I. The SF-36 health survey questionnaire: an outcome measure suitable for routine use within the NHS? BMJ 1993, 306: 1440-1444.

CHAPTER NINE

ASSESSMENT OF DEVICE SAFETY

The safety of each device was evaluated by urinalysis and urine culture, physical examination and any spontaneously reported adverse events.

ADVERSE EVENTS

An adverse event was any undesirable clinical event occurring to a subject during the clinical trial, whether or not it was considered related to the devices under investigation. If no adverse event occurred during the period concerned, this was also noted. The following definitions of "severity" were used:

A Serious adverse event includes any event which is life-threatening or has resulted in

- Death
- Hospitalisation; initial or prolonged
- Disability
- Required intervention to prevent permanent impairment/damage.

Data recorded for all types of adverse events included:

- type of adverse event
- duration
- severity
- action taken
- outcome
- causality
- seriousness

Mild adverse event - awareness of symptoms/signs, but easily tolerated (acceptable).

Moderate adverse event - enough discomfort to interfere with usual activity (disturbing).

Severe adverse event - incapacity to work or to do usual activity (unacceptable).

WITHDRAWAL FROM TREATMENT

A patient was withdrawn from the study treatment if, in the opinion of the investigator, it was medically necessary, or if it was the wish of the patient.

The following situations were accepted as criteria for withdrawal:

- Insufficient efficacy requiring withdrawal from treatment.
- Adverse event where the clinical opinion was to withdraw the treatment, including concurrent diseases.
- Major protocol violation occurring during the course of the study.
- Ineligibility; women who after start of study treatment were found to have violated a major inclusion/exclusion criterion.
- Consent withdrawn.
- Lost to follow-up; patient does not show up to a scheduled visit and all contact is broken thereafter.

CYSTITIS

Cystitis is a term used to describe inflammation of the urinary bladder. The inflammatory response arises in a variety of clinical situations and may have an infectious or non-infectious aetiology. Infections cystitis may be classified as acute, chronic or recurrent infection. It broadly describes the inflammatory response to microbiological invasion of the bladder, encompassing not only the clinical symptoms of urinary frequency, urgency and dysuria. Infection is characterised by large numbers of organisms and leucocytes in the urine with varying significance and severity. The natural history of the disease depends on the type of urinary pathogen, its virulence and resistance to antimicrobial agents, as well as certain host factors and

special circumstance. Diagnosis is based on the clinical manifestations, microscopic examinations, non-culture techniques as well as the results of urine culture. It may require the use of certain criteria to make an accurate diagnosis. The principles of management are to verify the diagnosis and select the appropriate antimicrobial agent most likely to be effective.

Prevalence

Bacterial cystitis is the most common bacterial infection occurring in women. It has been estimated that women have at least a 50% chance of developing at least one urinary infection during their lifetime [1]. Studies have also shown that the prevalence of bacteriuria in schoolgirls is one to two percent, about ten times higher than boys [2 3].

URETHRITIS

This is defined as inflammation of the urethra. Women may complain of retropubic pressure, dyspareunia, diurnal urinary frequency, dysuria, and urethral irritation [4]. The micro-organisms isolated from cases of urethritis show the same virulence factors as those seen in uropathogens causing acute cystitis. It should be noted that inflammation is often not limited to the urethra but may also involve the bladder wall [5].

Instrumentation of the urinary tract

Inflammatory reactions of the urethral wall are also known to occur by repeated introductions of a catheter or catheter like devices in the urethra. This may result in minor degrees of inflammation to frank urethritis and post inflammatory urethral stricture formation [6]. There is approximately a 5 percent incidence of urinary tract infection and cystitis following catheterisation of a normal bladder, despite a sterile technique. This is modified by the duration of catheterisation as well as the general well being of the patient [7]. Indeed, with long-term follow-up, urethritis has been reported to occur in up to 19% of patients performing CISC [8].

Microbiological terminology

The urinary stream may become contaminated by small numbers of bacteria hence the term "bacteriuria" which means bacteria in the urine, regardless of source.
Bacteriuria may or may not be associated with symptoms and the presence of pyuria.
From a clean freshly voided specimen of urine, one may expect less than 10,000 colony-forming units (cfu) per ml. Kass (1956) proposed a useful cut off point of 100,000 cfu/ml to define significant bacteriuria so as to differentiate it from contamination [9].
There is much debate regarding the significance of bacterial colonisation of urine versus infection. A concentration of 10^2 cfu/ml can cause an acute urinary tract infection in the healthy woman [10].

Urine collection

There is no standard method of collection, transport or processing of urine specimens or reporting of results. Contamination of the specimen may occur if the urine flushes onto the vulva and vagina. This may be minimised by instructing the woman to separate the labia and wash and dry the periurethral region. She should void with the labia spread and collect a mid-stream specimen. This method can provide reliable specimens and was utilised in this study.

Urinalysis

Urinalysis may provide additional supportive evidence of cystitis to allow a pre-emptive diagnosis of infection. Some of the elements of information provided by urinalysis are more valuable than others. For instance, cloudy urine indicates white cells or crystals and can be due to the presence of bacteria but this is unreliable.

Proteinuria

Dipstick tests for proteinuria have a poor predictive value in detecting renal disease due to their low specificity. Up to 6% of school children have proteinuria and the

rates rise with age [11]. The presence of proteinuria is more a reflection of renal disease and is not normally judged a sign of bladder infections.

Pyuria

Pyuria implies the presence of polymorphonuclear leucocytes in the urine. When viewed under the microscope more than two white cells per high-powered field represents abnormal pyuria. It may be helpful in the interpretation of the clinical significance of urine culture results [12]. Detection of pyuria is a helpful pointer to the presence of infection with 96.6% of symptomatic bacteriuric patients having ten or more white cells per mm^3 compared to 1.6% in abacteriuric asymptomatic subjects [13]. An MSU with greater than 10 pus cells per hpf has an 87% chance of being infected compared with 10% in specimens with less than two pus cells per phf [14]. In the absence of pyuria, one should question the diagnosis of infective cystitis.

Haematuria

The presence of red blood cells commonly occurs when there is an infection in the mucosa of the bladder wall. It tends to occur in association with bacteriuria and pyuria. Of normal urine samples, 90% have less than one red blood cell per high power field. More than 3 red blood cells per high power field usually signify an abnormality of the urinary tract [15].

Urine Culture

A mid stream specimen of urine (MSU) for culture was taken at each visit. Women with symptomatic urinary tract infection (UTI) were treated before inclusion in the study. Any UTI that developed during the study was treated and device use discontinued until there was clinical and microbiological cure.

PETECHIAL HAEMORRHAGES

VASCULAR FRAGILITY

The ability of capillary walls to withstand distending pressure may be reduced in a wide variety of general diseases; including infection and trauma. Some women have an increased susceptibility and bruise more readily than others. An increased bruising tendency is not uncommon in the elderly [16].

BRUISE

Bruises are due to blood leaking from vessels into the dermis. They result when blood vessels are sufficiently damaged for red blood cells to escape into the surrounding connective tissue. The breakdown of haemoglobin provides the colour changes associated with the lesion [17].

Bruises are classified according to their shape and size. Petechiae are small bruises or pinpoint haemorrhages that occur in the subcutaneous or submucosal tissues. The petechiae are tiny because the endothelial lesion is contained by the supporting perivascular tissue. The mechanisms involved are due to trauma of sufficient power to damage normal vessels, as a result of minor trauma to fragile vessels in the elderly, or because the supporting tissue has become defective.

Ecchymosis are large, more diffuse haemorrhagic areas. These clot haemorrhages do not blanch with pressure.

References

[1] Asscher AW. The challenge of Urinary Tract Infections. London: Academic Press 1980;14.

[2] Kass E, Savage W, Santamarina B. The significance of bacteriuria in preventive medicine. In Kass E (Ed), Progress in pyelonephritis. Davis, Philadelphia p 3-10.

[3] Mayon-White R. Asymptomatic bacteriuria in childhood: a review of recent and current studies. In Kass E, Brumfitt W (Eds). Infection of the urinary tract. University of Chicago Press, Chicago pp 22-25.

[4] Gittes R, Nakamura R. Female urethral syndrome. A female prostatitis? West J Med 1996;164(5):435-8.

[5] Tait J, Peddie B, Bailey R et al. Urethral syndrome (abacterial cystitis)-search for a pathogen. Br J Urol 1985; 57:552-556.

[6] Sharfi A, Elarabi Y. The "watering can" perineum: presentation and management. B J Urol 1997;80(6):933-6.

[7] Warren J, Platt R, Thomas R, et al. Antibiotic irrigation and catheter-associated urinary tract infections. N Engl J Med 1978; 299: 570 –577.

[8] Wyndaele J, Maes D. Clean intermittent self-catheterisation: a 12-year follow-up. J Urol 1990;143:906-908.

[9] Kass EH. Asymptomatic infections of the urinary tract. Trans Assoc Am Physicians 1956; 69: 56-64.

[10] Kunin CM, White LV, Hua TH. A reassessment of the importance of the "low count" bacteriuria in young women with acute urinary symptoms. Annals Int Med 1993; 119(6):454-60.

[11] Wagner MG, Smith FG, Tinglof BL et al. Epidemiology of proteinuria – A study of 4,807 school children – J Paediat 1968; 73:825 – 832.

[12] Morgan MG, McKenzie H. Controversies in the laboratory diagnosis of community-acquired urinary tract infection. Eur J Clin Microbiol and Infect Dis. 1993;12(7):491-504.

[13] Stamm WE. Quantitative urine cultures revisited. Eur. J Clin Microbiol 1984; 3: 279-281

[14] Maskell R, Polak A. Bacteriological facilities for the diagnosis of urinary infection in general practice. In: Brumfitt W, Asscher A (Eds). Urinary tract infections. Oxford University Press; Oxford pp3-10.

[15] Kliger A, Berns J. Renal problems. In Textbook of diagnostic medicine. Eds Samig A, Gordon-Douglas R, Barondess J. Lea & Febiger, Philadelphia, USA 1987.

[16] Roddie I, Wallace W. Abnormal bleeding (Haemorrhagic disorders) in Physiology of disease. Roddie I, Wallace W, eds. Lloyd Luke Ltd. London, 1974.

[17] Cotton D, Skin In General and Systematic Pathology. Underwood J, Ed. 2nd Ed. Churchill Livingstone, UK, 1996.

CHAPTER TEN

OBJECTIVE RESULTS FOR
THE RELIANCE AND FEMASSIST DEVICES

OBJECTIVE RESULTS FOR
THE RELIANCE AND FEMASSIST DEVICES

The results will be presented under the following headings;

Presentation of results

Baseline Data Comparable

Domains of patient observations with device use
- Foreign body sensation
- Ease of placement and comfort of device use

Control of incontinence
- Urine loss with specific activities
- Overall degree of dryness

Domains of clinicians observations
Quantification of urine loss
- Incontinence episodes per day
- Continence pads used over 5 days
- Pad weight test gains

Change in urethral function as a consequence of device use

Further comparison of Reliance & FemAssist groups

Quality of life and impact of symptoms

Adverse events

Table 10.1 Presentation of results

BASELINE DATA COMPARABLE

The two groups were evaluated before the interventions to check that they were comparable in respect of features known to affect outcome: age, parity, menopausal status and the use of oestrogen replacement therapy and the severity of incontinence [number of incontinence episodes per day, the number of continence pads used per 5 days recorded in the urinary diary and PWT gains]. As these are independent samples, the statistical analysis was performed using the non-parametric Wilcoxon rank test as described previously.

AGE

I assessed whether there was any difference in the ages of women in each group. Calculations were made using the Wilcoxon rank sum test for independent samples. There was no difference in the median ages of the subjects in each group. Also, the age distributions were roughly the same in each group (table10.2 & 10.3).

Groups	Total	Min	Max	Median
Reliance	**48**	**32**	**65**	**50.6**
FemAssist	**53**	**30**	**77**	**49.8**
Aggregated Data	**101**	**30**	**77**	**50.2**

Table 10.2 The age of patients at study inclusion for each group /and for the aggregated data. (Min=minimum, Max=maximum.)

Age (years) distribution at study inclusion							
Age Groups	**21-30**	**31-40**	**41-50**	**51-60**	**61-70**	**71-80**	**Total**
Reliance	1 (2%)	8 (16.7%)	21 (43.7%)	15 (31.3%)	3 (6.3%)	0	48
FemAssist	1 (1.9%)	10 (18.9%)	21 (39.6%)	16 (30.2%)	4 (7.5%)	1 (1.9%)	53

Table 10.3 The patient age distribution at study inclusion for each group.

MENOPAUSAL STATUS AND USE OF OESTROGENS

The menopause status of the women in each group and the use of hormone replacement therapy (HRT) are presented in table 10.4. The data for the groups combined is also presented. The study patients were well matched for menopausal status and the use of oestrogens.

Menopausal status and use of oestrogen replacement therapy		
Groups	**Menopausal**	**Treated with oestrogens**
Reliance	**27(56.3%)**	**19(39.6%)**
FemAssist	**21(39.6%)**	**14(26.4%)**
Total	**48(47.5%)**	**33(32.7%)**

Table 10.4 The menopausal status and use of oestrogen replacement therapy at study inclusion for each group and for the groups when aggregated. The Wilcoxon rank sum test statistic was employed.

All subjects in both groups were parous.

BASELINE SEVERITY OF INCONTINENCE

The baseline severity of incontinence was assessed by analysis of the number of incontinence episodes per day and the number of continence pads used per five days recorded in the urinary diary and the PWT gains prior to the use of devices.

URINARY DIARY

1 INCONTINENCE EPISODES

I assessed whether or not there was any difference in the severity of incontinence between the two groups on entry to the study based on the number of incontinence episodes per day recorded in the urinary diary.

Null Hypothesis

The median numbers of incontinence episodes per day at baseline in both groups before use of a device are equal.

Number of incontinence episodes experienced at study inclusion for each group (Reliance and FemAssist)				
	MIN	**MAX**	**MEDIAN**	**Paired differences p-value**
Reliance n=48	4	7	5.1	0.18
FemAssist n=53	4	8	4.9	

Table 10.5 The number of incontinence episodes experienced at study inclusion for each group (Reliance and FemAssist) is illustrated. [MIN = minimum, MAX = maximum]

There was no statistical difference in the number of incontinence episodes experienced between the groups based on the data in the urinary diary (Table 10.5).

2 CONTINENCE PADS USED

I assessed whether or not there was any difference in the severity of incontinence between the two groups on entry to the study based on the number of continence pads used per five days recorded in the urinary diary.

Null Hypothesis

The median number of continence pads at baseline in both groups before use of a device is equal.

Number of continence pads used at study inclusion for each group (Reliance and FemAssist)				
	MIN	**MAX**	**MEDIAN**	**Paired differences P-value**
Reliance n=48	8	12	10.6	0.22
FemAssist n=53	8	15	11.1	

Table 10.6 The number of continence pads used per five days at study inclusion for each group (Reliance and FemAssist) is illustrated. [MIN = minimum, MAX = maximum]

There was no statistical difference in the number of continence pads used by women in the two groups based on the data in the urinary diary (Table 10.6)

3 PAD WEIGHT TEST GAINS

Pad weight test data at study inclusion for each group prior to use of a device is presented in table10.7. Assessment was made of whether or not there was any difference in the severity of incontinence between the two groups, FemAssist and Reliance, on entry to the trial based on their PWT gains. The null Hypothesis is that the median PWT gains at baseline in both groups before use of a device are equal.

Baseline pad weight test data for each group (Reliance and FemAssist) prior to device use				
	MIN	**MAX**	**MEDIAN**	**Paired differences P-value**
Reliance n=48	0.8	99	31.2	0.43
FemAssist n=53	1.1	128	28.3	

Table 10.7 The baseline pad weight test data for each group (Reliance and FemAssist) prior to device use is illustrated. [MIN = minimum PWT gain, MAX = maximum PWT gain]

PRODUCT USE

FEMASSIST DEVICE

We were unable to ascertain accurately how many applications patients performed in one day as they were not compliant in recording these events. The impression was that they applied the device frequently for shorter periods than the Reliance. Each subject used approximately one device over the course of seven days. However the vast majority felt that the FemAssist was in good condition, worked well and could be used for much longer periods. During the 6 months period approximately 948 FemAssist devices were used.

RELIANCE DEVICE

In the first month 42 women used 2,772 devices at a mean rate of 2.2 per day. In the next two months 29 women used 4,350 devices at a mean rate of 2.5 per day. In the

next three months 31 women used 2,772 devices at a mean rate of 2.1 per day (total 12,981).

DOMAINS OF PATIENT OBSERVATIONS WITH DEVICE USE

FOREIGN BODY SENSATION

There was a reduction in foreign body sensation while wearing the device over time in both groups. After 1 month, 9 (20.5%) women experienced a bothersome foreign body sensation with the Reliance and 11 (23.4%) with the FemAssist device, which reduced slightly in both groups at 3 months. At the end of the study 5 (16.1%) women noted this foreign body sensation with the Reliance and 5 (13.9%) with the FemAssist devices respectively. The results are illustrated in table 10.8. If women noted this sensation initially, then it resolved over time. If they did not note it at the beginning of the study, it did not arise over time with sustained use of the devices (Figure 10.1). Once a device was removed, there was no residual foreign body sensation if this was felt with device use.

	Foreign body sensation while wearing The devices over time		
	1 MONTH	**3 MONTHS**	**6 MONTHS**
Reliance	9(20.5%)	7(21.2%)	5(16.1%)
FemAssist	11(23.4%)	7(17.1%)	5(13.9%)
No. in each group at each visit			
Reliance	42	29	31
FemAssist	47	41	36

Table 10.8 The incidence of bothersome foreign body sensation experienced while wearing a device as recorded at each visit. The numbers in the groups at each assessment visit are also recorded.

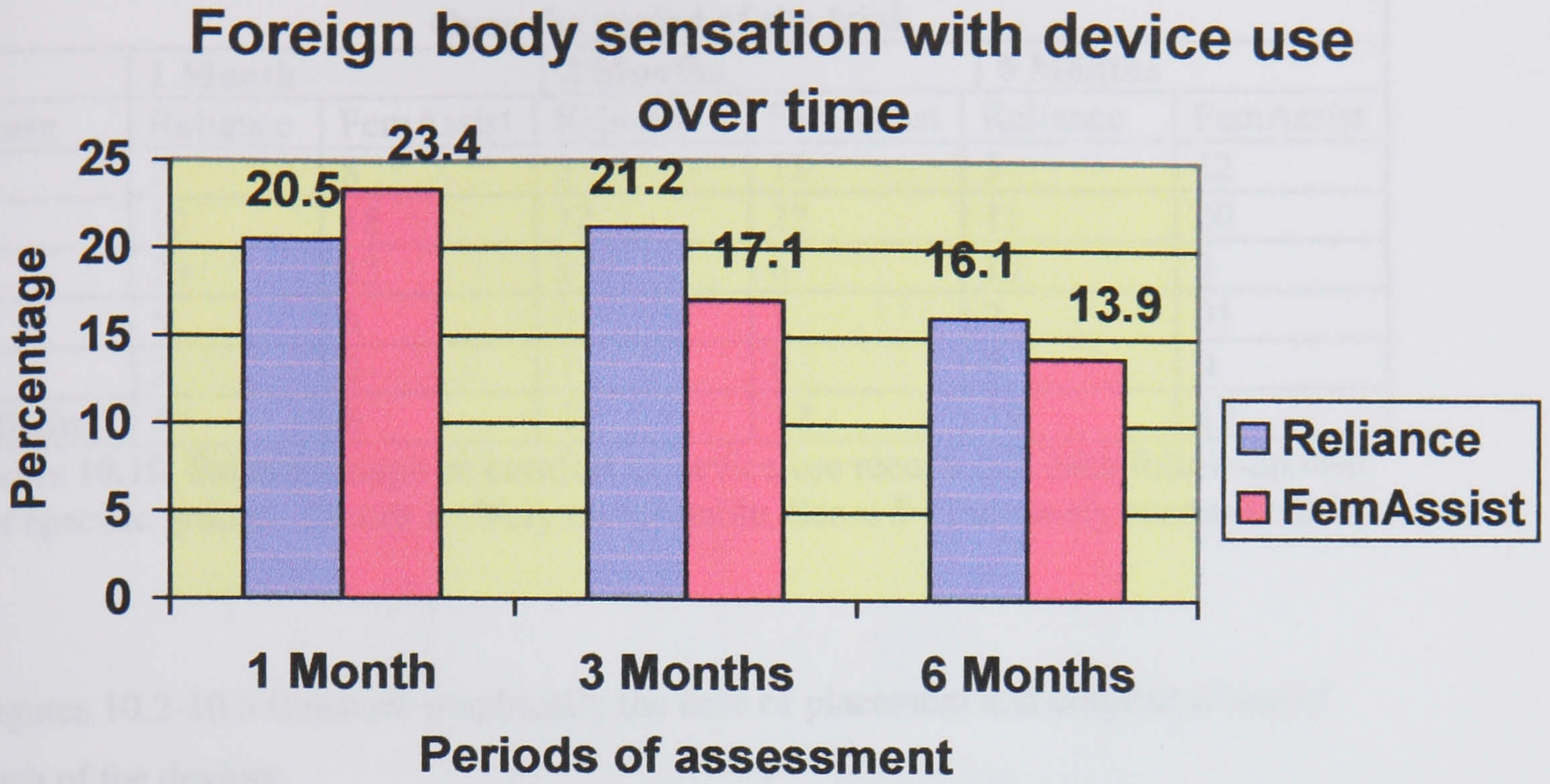


Figure 10.1 Percentage of women experiencing a foreign body sensation over the duration of the study. Analysis based on the number using device at any given point in time.

EASE AND COMFORT OF DEVICE USE

Patient ratings on ease of device placement and comfort of use recorded at each follow-up visit are shown in tables 1 - 7. Over time, it would appear that there is a trend for the devices to become more comfortable to wear and easier to place (Table 10.9 & 10.10).

Patient rating of "ease" of placement of each device Over the period of the trial						
	1 Month		**3 Months**		**6 Months**	
Score	Reliance	FemAssist	Reliance	FemAssist	Reliance	FemAssist
1	4	8	6	14	5	17
2	23	24	14	23	15	16
3	12	10	8	2	10	2
4	4	3	1	2	1	1
5	1	2	0	0	0	0
Missing	4	6	19	12	17	17

Table 10.9 Patient ratings on ease of device placement recorded at each follow-up visit for each group. (Score 1= Very easy, Score 5= Extremely difficult)

Patient rating of "comfort" of device use Over the period of the trial						
	1 Month		3 Months		6 Months	
Score	Reliance	FemAssist	Reliance	FemAssist	Reliance	FemAssist
1	2	8	5	12	5	12
2	12	18	12	22	11	20
3	23	13	11	6	13	3
4	5	6	0	1	2	01
5	2	2	1	0	0	0
Missing	4	6	19	12	17	17

Table 10.10 Patient ratings on comfort of device use recorded at each follow-up visit for specific groups. (Score 1= Very comfortable, Score 5= Extremely uncomfortable)

Figures 10.2-10.5 illustrate graphically the ease of placement and comfort of use of each of the devices.

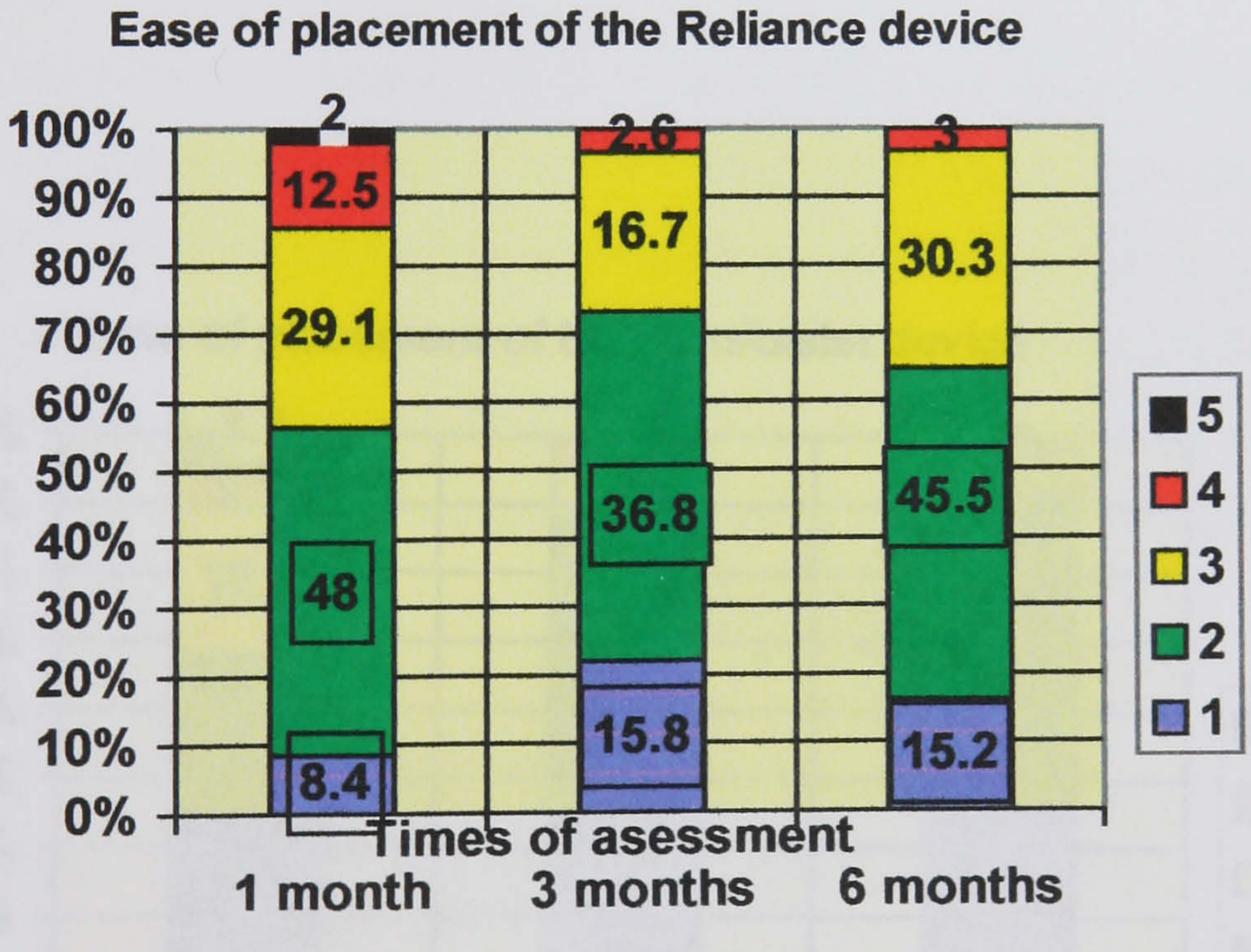


Figure 10.2 Patient rating on ease of placement of the Reliance device over time. Ease of placement rated on a scale of 1 to 5 (1 = Very easy; 5 = Extremely difficult).

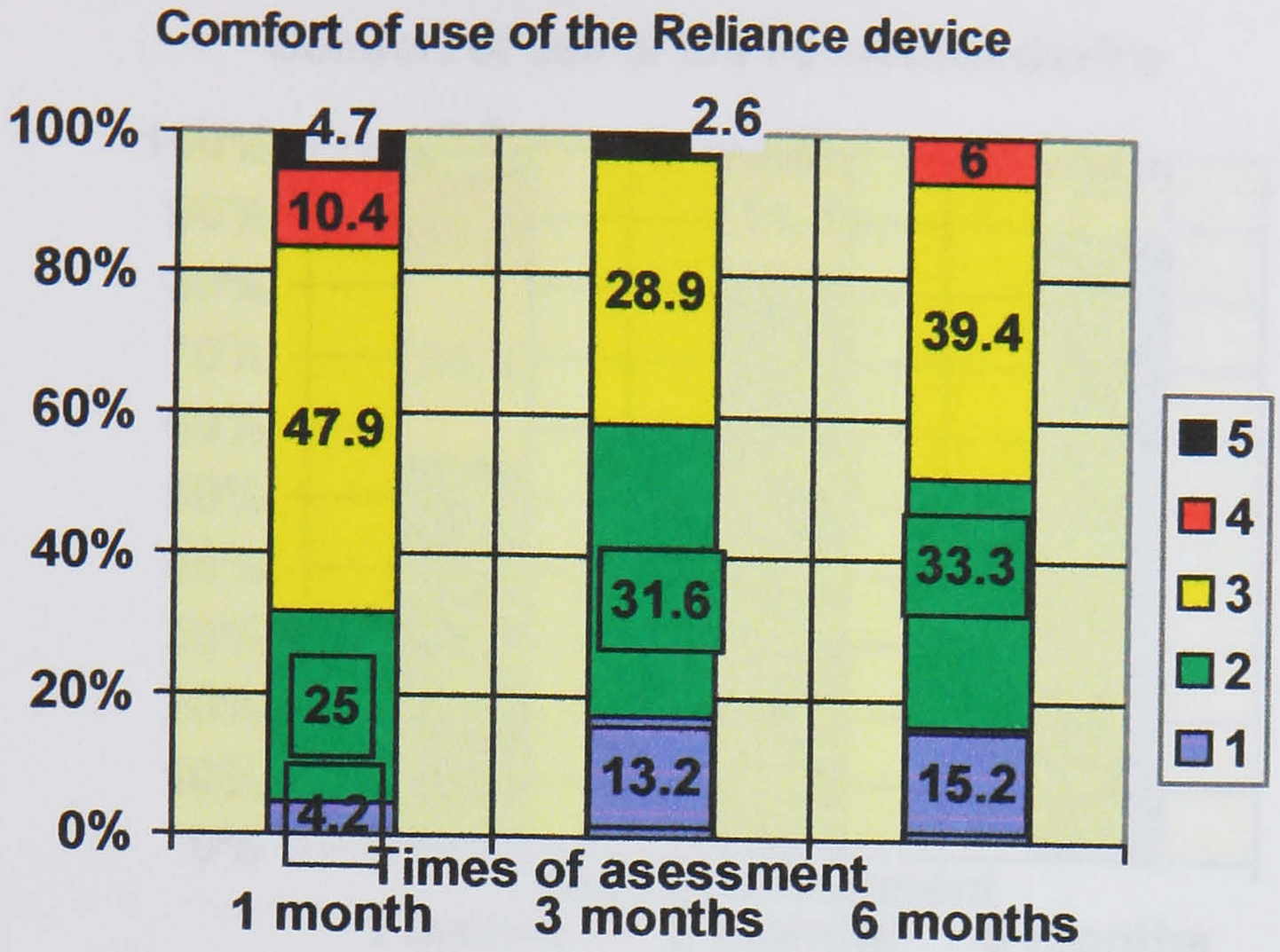


Figure 10.3 Patient rating on comfort of the Reliance device over time. Comfort level was rated on a scale of 1 to 5 (1 = Very comfortable; 5 = extremely uncomfortable).

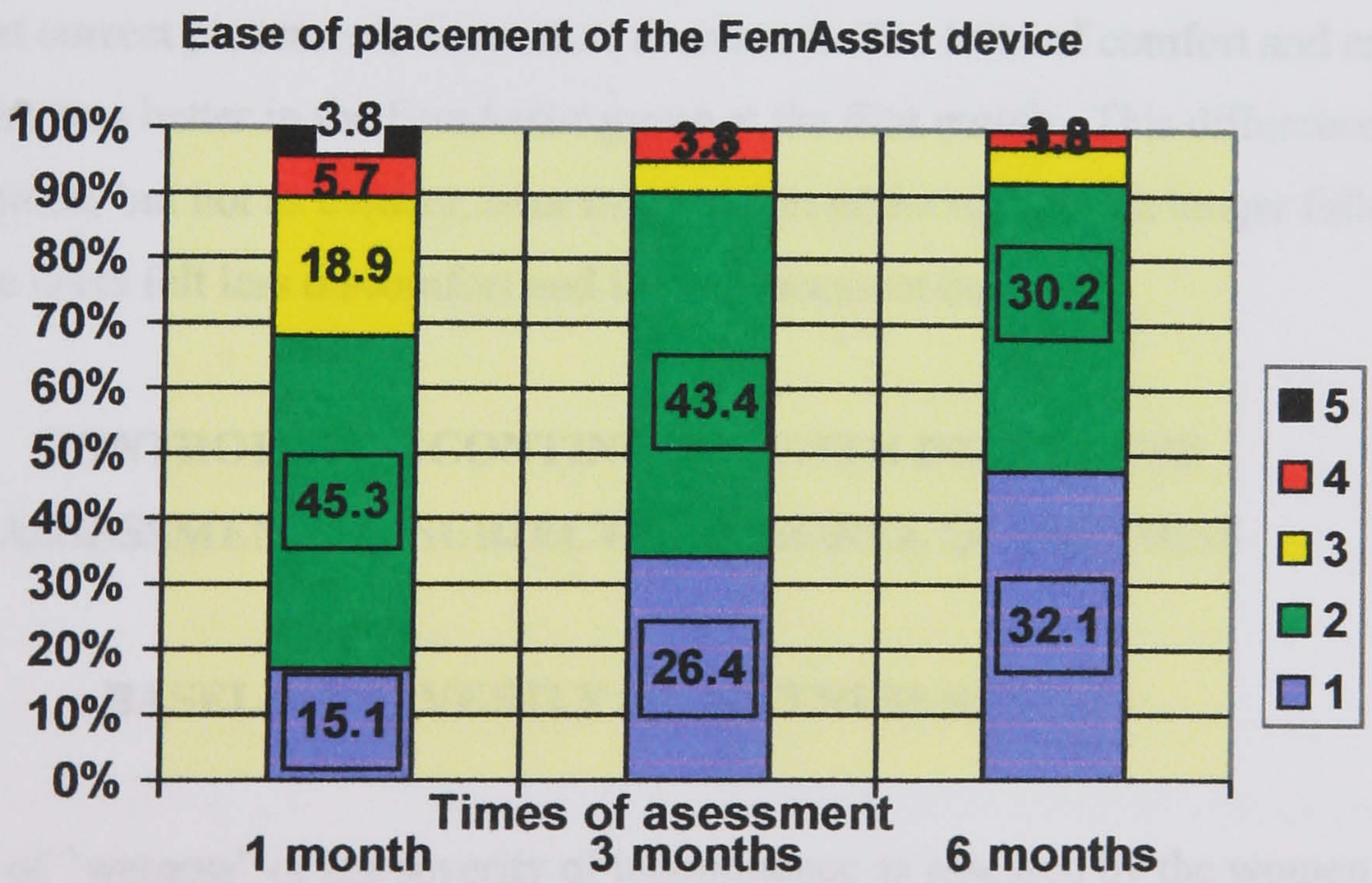


Figure 10.4 Patient rating on ease of placement of the FemAssist device over time. Ease of placement rated on a scale of 1 to 5 (1 = Very easy; 5 = Extremely difficult).

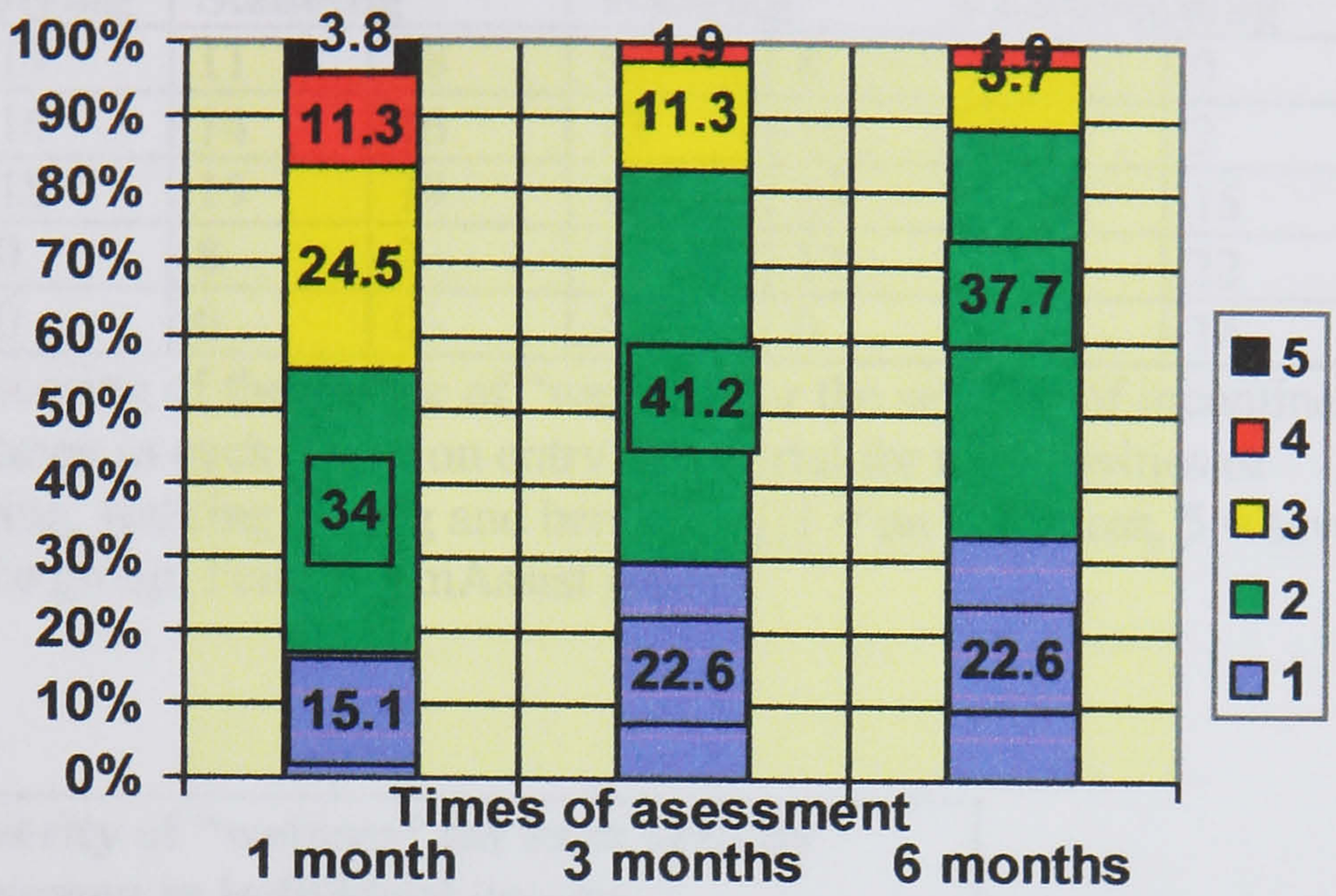


Figure 10.5 Patient rating on comfort of the FemAssist device over time. Comfort level was rated on a scale of 1 to 5 (1 = Very comfortable; 5 = extremely uncomfortable).

Most women demonstrated a reasonably high mean response to comfort of use. There was a slightly better response at month 6 compared to months 1 and 3, primarily attributed to initial inadequate device placement. As the women become more proficient at correct placement, discomfort decreased. The level of comfort and ease of placement was better in the FemAssist group at the first month. This difference was maintained, but not as evident, over the duration of the trial. With longer follow-up Reliance users felt less discomfort and found placement easier.

CONTROL OF INCONTINENCE WITH DEVICE USE

ASSESSMENT OF SUBJECTIVE DEGREE OF DRYNESS

BASELINE SEVERITY OF WETNESS SCORES

The degree of "wetness" or the severity of incontinence as assessed by the women in each group on entry to the trial is given in tables 10.11 and 10.12. Each activity was scored as described in the chapter on methods of analysis.

Baseline severity of "wetness" for each activity Of women in individual groups								
Score	**Rel**	**Fem**	**Rel**	**Fem**	**Rel**	**Fem**	**Rel**	**Fem**
	Sitting/lying		**Standing**		**Walking**		**Lift/bending**	
1	17	19	11	18	5	8	2	0
2	11	16	14	16	13	14	2	2
3	17	18	15	19	14	14	16	15
4	3	0	8	0	14	17	19	22
5	0	0	0	0	2	0	9	14

Table 10.11 The scoring of the degree of "wetness" or the severity of incontinence as assessed by the women in each group on entry to the trial for the activities of sitting/lying, standing, walking, lifting and bending. [(1 = no urine loss, 5 = severe loss) Rel = Reliance group, Fem = FemAssist group]

Baseline severity of "wetness" for each activity of women in individual groups						
Score	**Rel**	**Fem**	**Rel**	**Fem**	**Rel**	**Fem**
	Low impact Exercise		**High impact Exercise**		**Cough/sneeze/ Laugh**	
1	2	0	0	0	1	0
2	1	2	0	2	1	1
3	6	11	0	11	2	12
4	22	24	5	22	4	22
5	17	16	40	18	40	18

Table 10.12 The scoring of the degree of "wetness" or the severity of incontinence as assessed by the women in each group on entry to the trial for the activities of low impact exercise, high impact exercise and coughing/sneezing/laughing. [(1 = no urine loss, 5 = severe loss) Rel = Reliance group, Fem = FemAssist group]

PATIENT RATED DRYNESS WITH SPECIFIC ACTIVITIES

The response to treatment as rated by the patients while performing specific groups of activities was categorised as "Completely Dry", "Significant improvement", "No better" or "Worse". The responses were defined in the chapter describing the methods of analysis, but are repeated for convenience; {"Completely Dry" with device use was computed as 1 (scale 1 to 5), "Significant improvement" was defined as >50% reduction in rating of urine loss during insert use (scale 1 to 5) compared with before insert use, "No better" was defined as no statistically significant change in the rating, "Worse" was defined as a statistically significant change in the rating in a less favourable direction}. The scores in response to treatment with each device as

rated by the patients while performing specific exercises is given in tables 4-6. The data illustrate the degree of protection afforded for the activities tested with the Reliance and FemAssist devices comparing baseline severity of "wetness" with that of device use at each subsequent visit (Tables 10.13 - 10.19). The percentages were analysed on an intention to treat basis. As shown, there was a significant increase in the percentage of patients reporting complete dryness or significant improvement with device use. The increase in dryness was evident for less strenuous manoeuvres such as sitting and standing but particularly so for the more provocative manoeuvres such as coughing, lifting, low and high impact exercise. A trend to increased patient participation in more provocative manoeuvres over time was also noted for both groups. No subject was made worse with device use in either group.

Patient rated dryness for the activities tested at each visit as a change from baseline severity of wetness with each device			
Sitting/ Lying	**1 month**	**3 month**	**6 month**
Reliance (no. at each visit)	42	29	31
Dry	42 87.5%	29 60.4%	31 64.6%
Significantly improved	0	0	0
No better	0	0	0
FemAssist(no. at each visit)	47	41	36
Dry	47 88.7%	41 77.4%	36 67.9%
Significantly improved			
No better			

Table 10.13 The degree of protection afforded for sitting/lying with the Reliance and FemAssist devices comparing baseline severity of "wetness" with that of device use at each subsequent visit.

Patient rated dryness for the activities tested at each visit as a change from baseline severity of wetness with each device			
Standing	**1 month**	**3 month**	**6 month**
Reliance (no. at each visit)	42	29	31
Dry	42 87.5%	29 60.4%	31 64.6%
Significantly improved	0	0	0
No better	0	0	0
FemAssist(no. at each visit)	47	41	36
Dry	44 83%	38 71.7%	34 64.2%
Significantly improved	3 5.7%	3 5.7%	2 3.8%
No better	0	0	0

Table 10.14 The degree of protection afforded for standing with the Reliance and FemAssist devices comparing baseline severity of "wetness" with that of device use at each subsequent visit.

Patient rated dryness for the activities tested at each visit as a change from baseline severity of wetness with each device			
Walking	**1 month**	**3 month**	**6 month**
Reliance (no at each visit)	42	29	31
Dry	40 87.5%	27 56.3%	29 60.4%
Significantly improved	2 4.2%	2 4.2%	2 4.2%
FemAssist(no. at each visit)	47	41	36
Dry	30 56.6%	31 58.5%	33 62.3%
Significantly improved	6 11.3%	6 11.3%	5 9.4%
No better	11 20.8%	4 7.5%	5 9.4%

Table 10.15 The degree of protection afforded for walking with the Reliance and FemAssist devices comparing baseline severity of "wetness" with that of device use at each subsequent visit.

Patient rated dryness for the activities tested at each visit as a change from baseline severity of wetness with each device			
Lifting/ Bending	**1 month**	**3 month**	**6 month**
Reliance (no. at each visit)	42	29	31
Dry	40 83.3%	27 56.3%	31 64.6%
Significantly improved	2 4.2%	2 4.2%	1 2.1%
No better	0	0	0
FemAssist(no. at each visit)	47	41	36
Dry	27 50.9%	31 58.5%	33 62.3%
Significantly improved	8 15.1%	6 11.3%	3 5.7%
No better	0	3 5.7%	0

Table 10.16 The degree of protection afforded for lifting/bending with the Reliance and FemAssist devices comparing baseline severity of "wetness" with subsequent visits.

Patient rated dryness for the activities tested at each visit as a change from baseline severity of wetness with each device			
Low impact exercise	**1 month**	**3 month**	**6 month**
Reliance (no. at each visit)	42	29	31
Dry	38 79.2%	27 56.3%	29 60.4%
Significantly improved	3 6.3%	2 4.2%	2 4.2%
FemAssist(no. at each visit)	47	41	36
Dry	22 41.5%	26 49.1%	28 52.8%
Significantly improved	14 26.4%	10 18.9%	2 3.8%
No better	11 20.8%	5 9.4%	6 11.3%

Table 10.17 The degree of protection afforded for low impact exercise with the Reliance and FemAssist devices comparing baseline severity of "wetness" with that of device use at each subsequent visit.

Patient rated dryness for the activities tested at each visit as a change from baseline severity of wetness with each device			
High impact exercise	**1 month**	**3 month**	**6 month**
Reliance (no. at each visit)	42	29	31
Dry	24 50%	12 25%	17 35.4%
Significantly improved	14 29.2%	14 29.2%	13 27%
No better	0	0	0
FemAssist(no. at each visit)	47	41	36
Dry	0	5 9.4%	5 9.4%
Significantly improved	10 18.9%	4 7.5%	1 1.9%
No better	37 69.8%	32 60.4%	30 56.6%

Table 10.18 The degree of protection afforded for high impact exercise with the Reliance and FemAssist devices comparing baseline severity of "wetness" with that of device use at each subsequent visit.

Patient rated dryness for the activities tested at each visit as a change from baseline severity of wetness with each device			
Cough/sneeze/ laugh	**1 month**	**3 month**	**6 month**
Reliance (no. at each visit)	42	29	31
Dry	31 64.6%	21 43.8%	19 39.6%
Significantly improved	11 22.9%	8 16.7%	12 25%
FemAssist(no. at each visit)	47	41	36
Dry	17 32.1%	19 35.8%	20 37.7%
Significantly improved	28 52.8%	20 37.7%	18 34%
No better	2 3.8%	2 3.8%	3 5.7%

Table 10.19 The degree of protection afforded for coughing/sneezing/laughing

with the Reliance and FemAssist devices comparing baseline severity of "wetness" with that of device use at each subsequent visit.

The bar charts below (Figures 10.6 & 10.7) illustrates the number of women who were dry or significantly improved with use of the Reliance and FemAssist devices while performing each activity at each period of assessment.

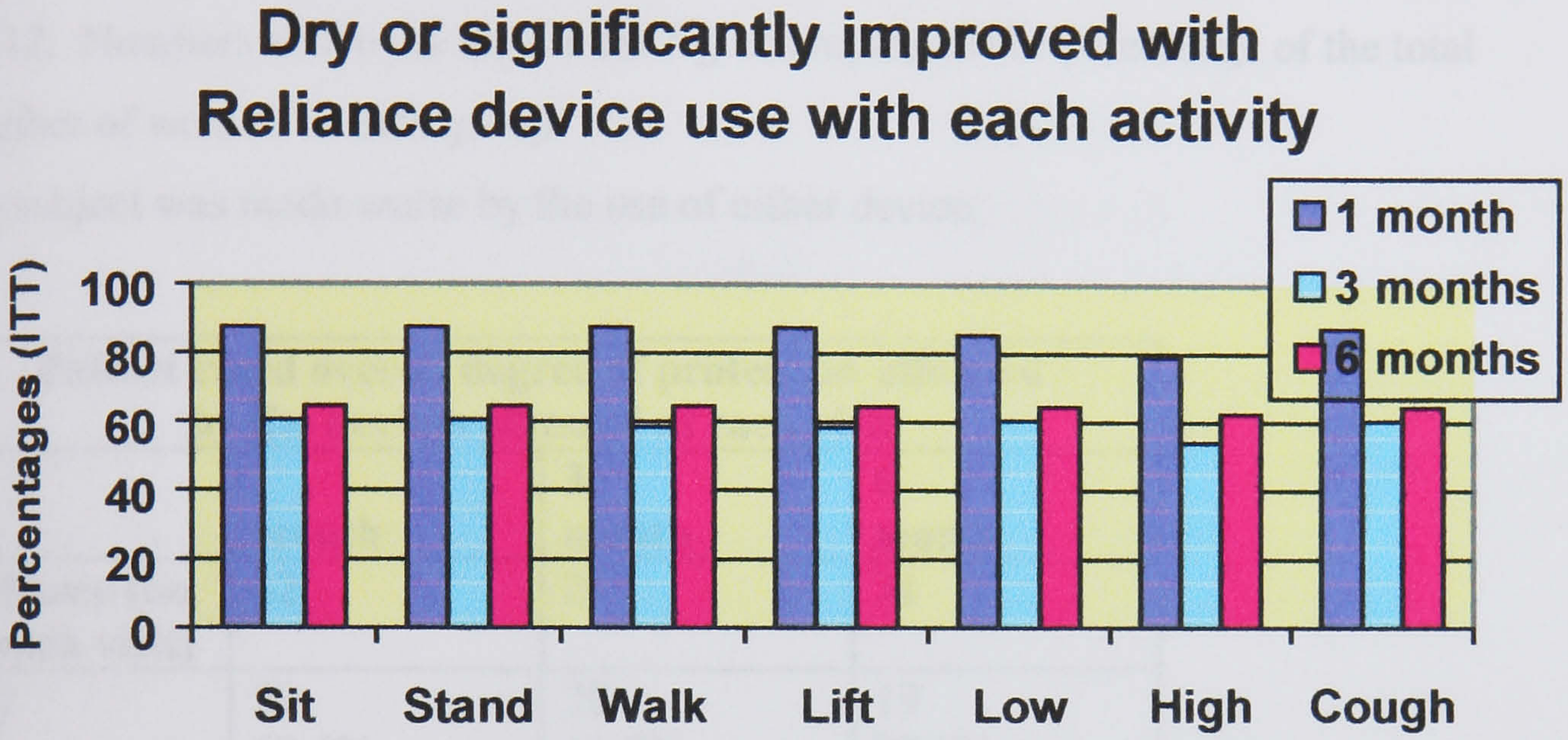


Figure 10.6 The number of women who were dry or significantly improved with use of the Reliance device while performing each activity at each period of assessment.

[ITT = Intention to treat basis]

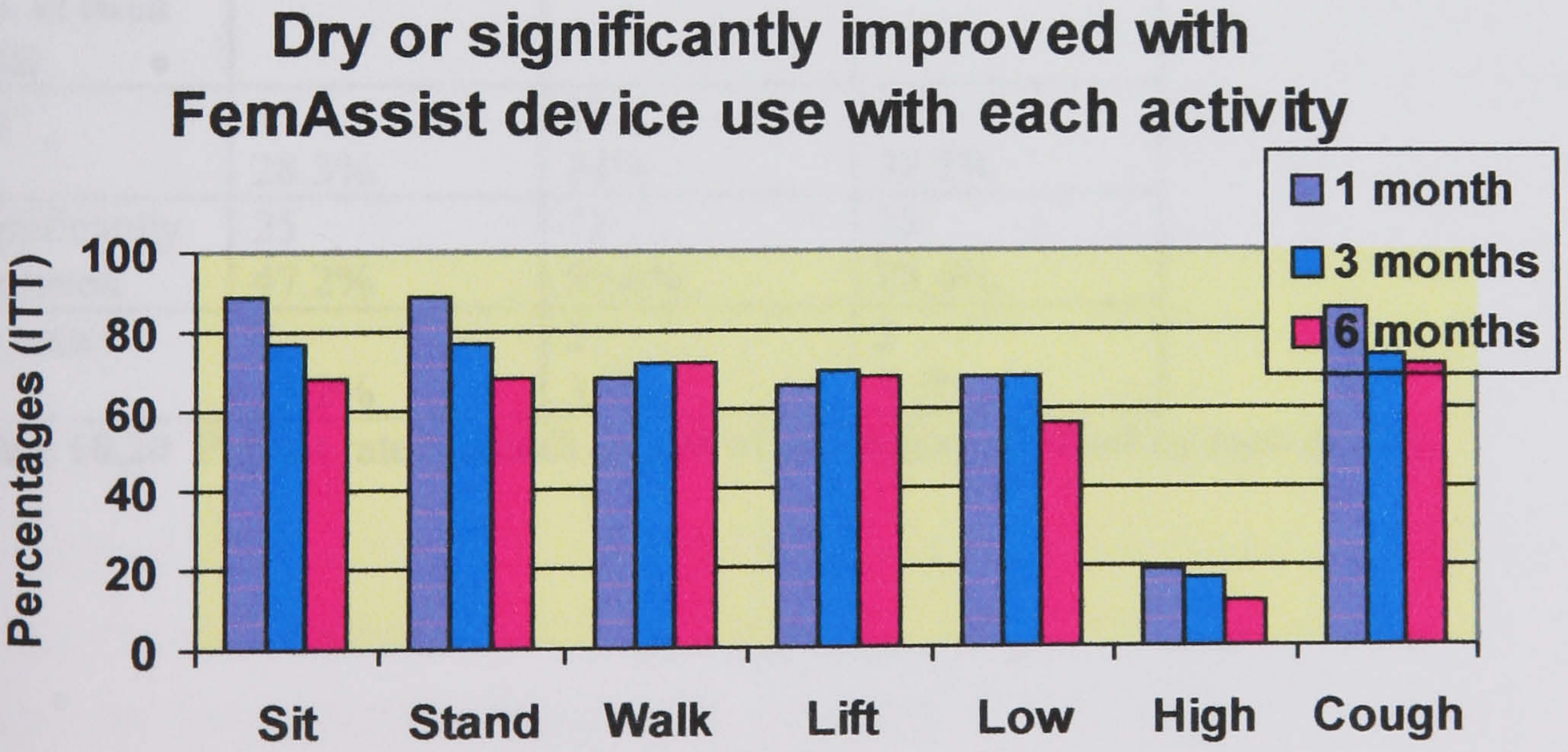


Figure 10.7 The number of women who were dry or significantly improved with use of the FemAssist device while performing each activity at each period of assessment.

[ITT = Intention to treat basis]

OVERALL DEGREE OF PROTECTION

The overall degree of protection afforded by each device as rated by the patients was similarly categorised as "Completely Dry", "Significant improvement", "No better" or "Worse" and defined in the chapter on methods of assessment. This was carried out at the 1, 3 and 6 months visits and is illustrated in table 10.20 and figures 10.8 – 10.12. Numbers above the bars in the figures represent the percentage of the total number of women in each group.

No subject was made worse by the use of either device.

Patient rated overall degree of protection afforded by the devices assessed at each visit			
	1 month	**3 month**	**6 month**
Reliance (no. at each visit)	42	29	31
Dry	29 60.4%	20 41.7%	19 39.6%
Significantly improved	10 20.8%	9 18.8%	12 25%
No better	3 6.3%	0	0
FemAssist (no. at each visit)	47	41	36
Dry	15 28.3%	18 34%	20 37.7%
Significantly improved	25 47.2%	21 39.6%	13 25.4%
No better	7 13.2%	2 3.8%	3 5.7%

Table 10.20 Patient rated overall degree of protection afforded by each device.

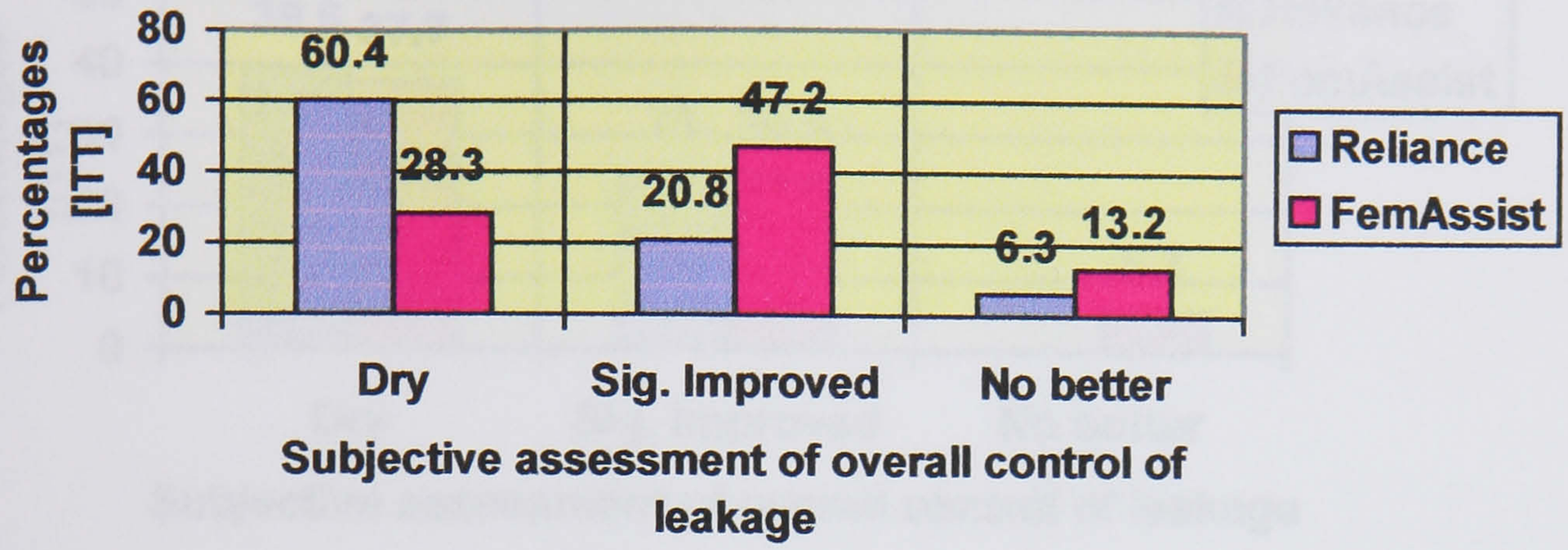


Figure 10.8 The subjective treatment outcome of women with GSI managed with the Reliance (n = 48) and FemAssist (n=53) devices. The overall degree of protection afforded by each device as assessed at one-month follow-up is illustrated.

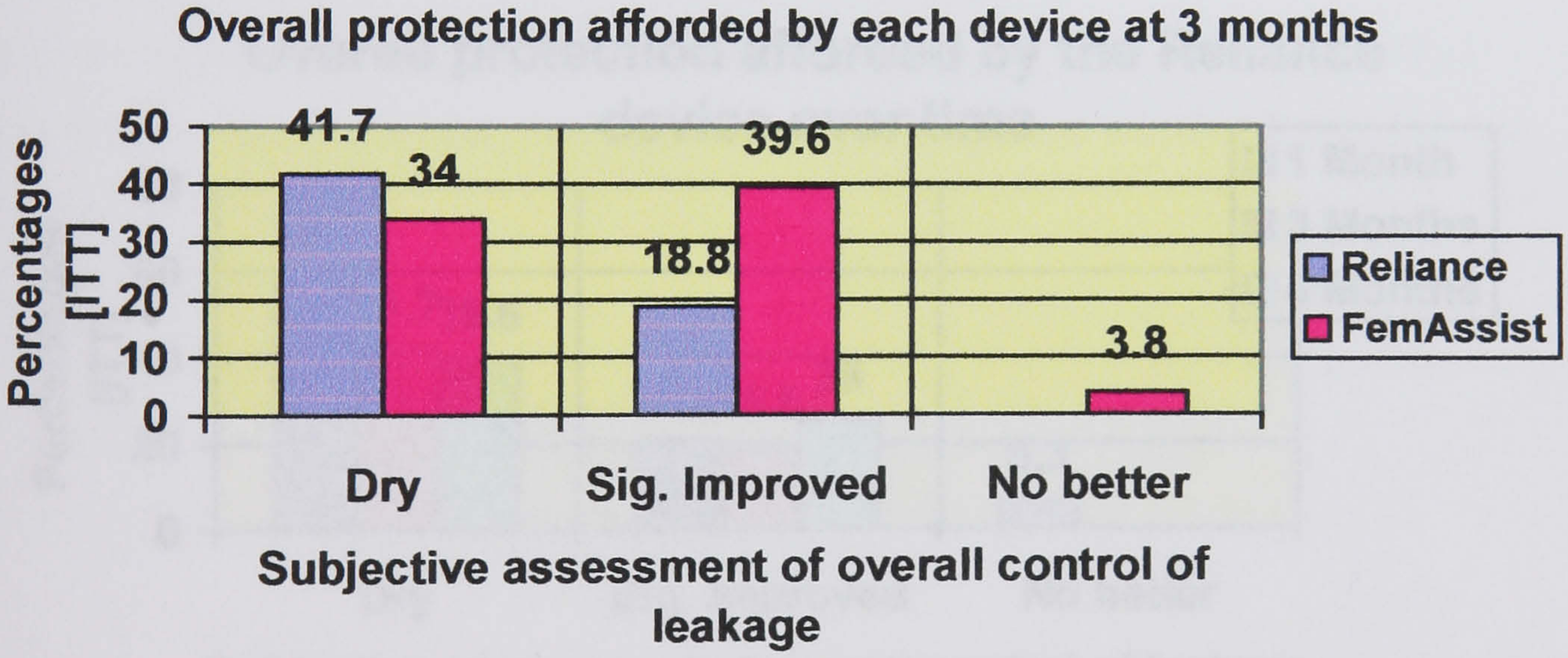


Figure 10.9 The subjective treatment outcome of women with GSI managed with the Reliance (n=48) and FemAssist (n=53) devices. The overall degree of protection afforded by each device as assessed at three months follow-up is illustrated.

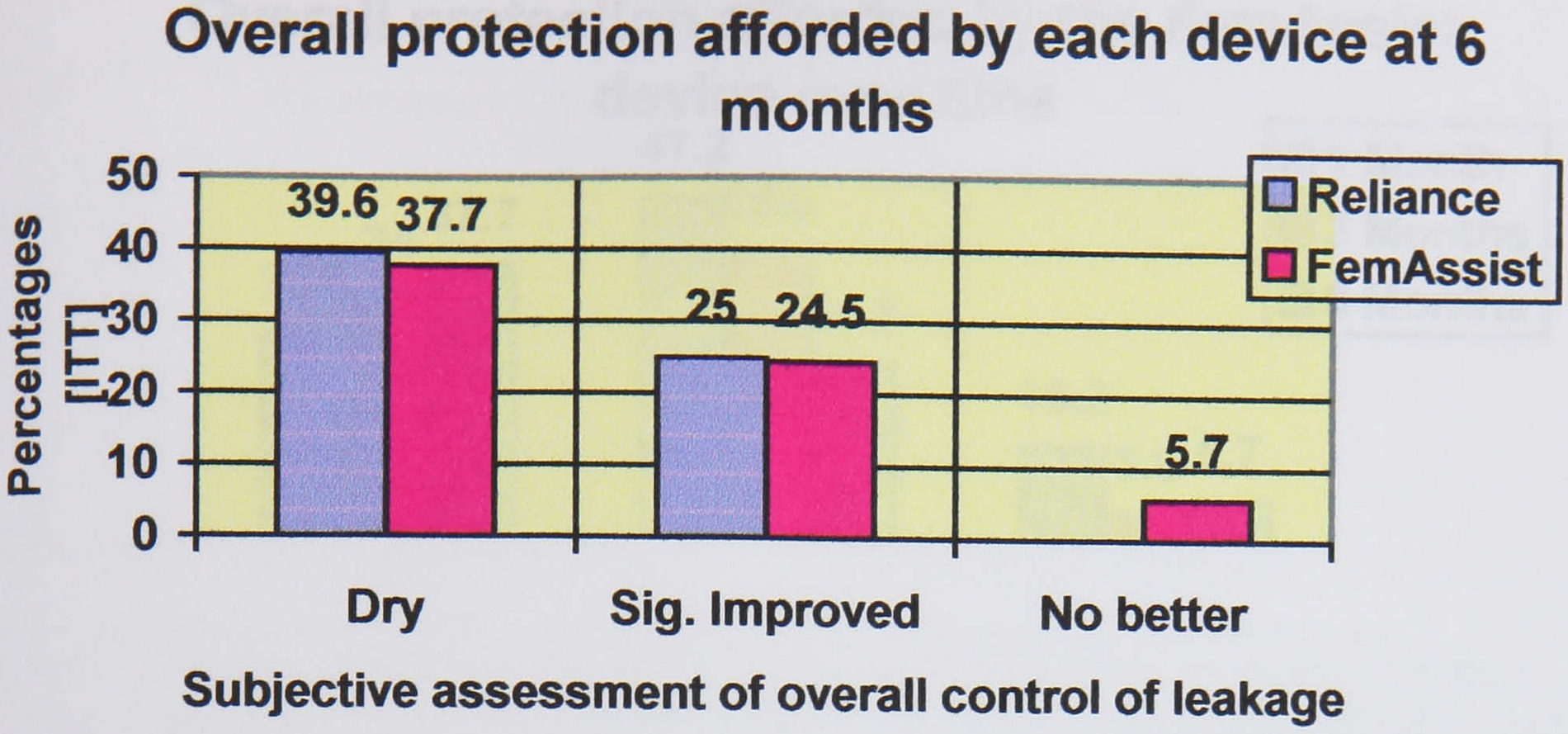


Figure 10.10 The subjective treatment outcome of women with GSI managed with the Reliance (n=48) and FemAssist (n=53) devices. The overall degree of protection afforded by each device as assessed at six months follow-up is illustrated.

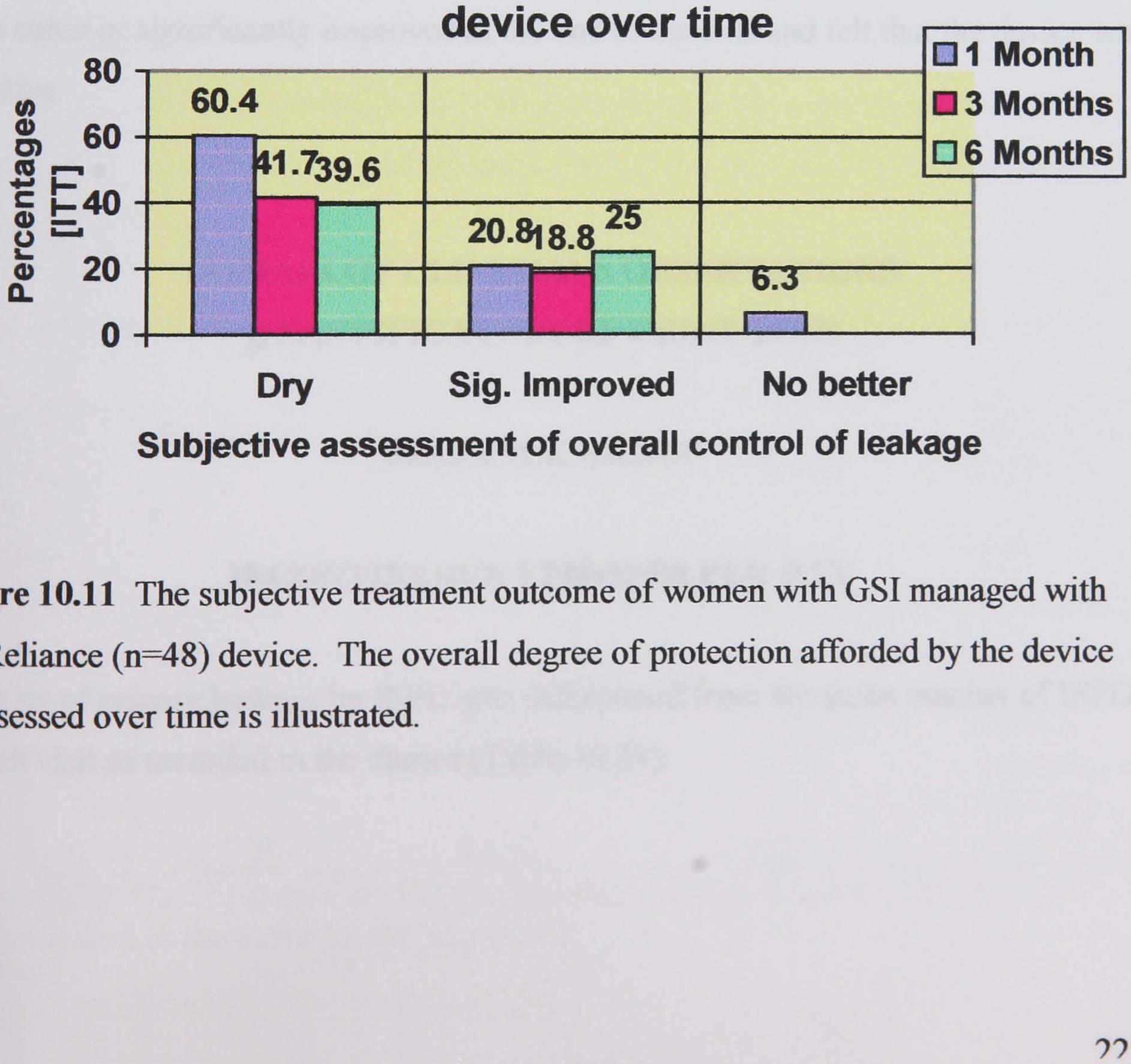


Figure 10.11 The subjective treatment outcome of women with GSI managed with the Reliance (n=48) device. The overall degree of protection afforded by the device as assessed over time is illustrated.

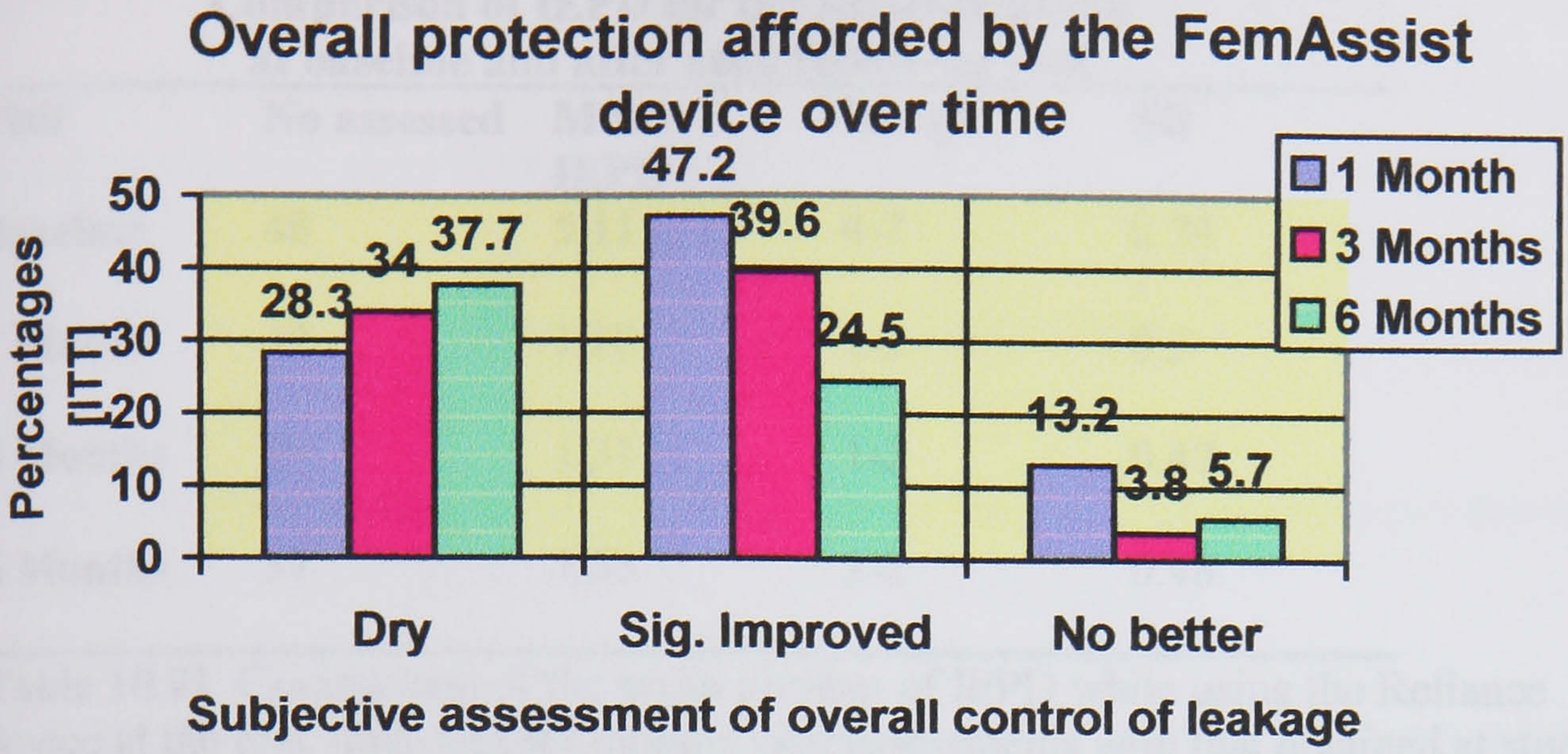


Figure 10.12 The subjective treatment outcome of women with GSI managed with the FemAssist (n=53) device. The overall degree of protection afforded by the device as assessed over time is illustrated.

Of all the women treated with a Reliance device (n=48), 31(64.6%) women felt that they were cured or significantly improved at the end of the trial and felt that the device was effective.

Of all the women treated with a FemAssist device (n=53), 33(62.3%) felt that they were cured or significantly improved at the end of the trial and felt that the device was effective.

DOMAIN OF CLINICIANS OBSERVATIONS

QUANTIFICATION OF URINE LOSS

RELIANCE GROUP

INCONTINENCE EPISODES PER DAY

Analysis of urinary leakage by IEPD was determined from the mean number of IEPD at each visit as recorded in the diaries (Table 10.21).

Comparison of IEPD for the Reliance group at baseline and after each follow-up visit				
Visit	**No assessed**	**Mean IEPD**	**Range**	**SD**
Baseline	48	5.11	4-7	0.74
1 Month	42	1.58	1-2	0.5
3 Months	29	1.31	1-2	0.47
6 Months	31	1.33	1-2	0.48

Table 10.21 Comparison of the mean number of IEPD while using the Reliance device at the one, three and six months visit assessments with that obtained at study inclusion.

I assessed whether or not there was any difference in the degree of protection afforded by the Reliance device as assessed by the number of incontinence episodes per day (IEPD) on the urinary diary at baseline without a device and after one, three and six months while using the device.

BASELINE VS 1 MONTH IEPD

Null Hypothesis

The means of the two populations, incontinence episodes per day at baseline and at one month, are equal. The table shows the mean IEPD recorded at baseline and after one month's device use.

Comparison of IEPD for the Reliance group at baseline and after 1 month (n=42)					
Variable	**No of pairs**	**Mean**	**Range**	**SD**	**SE of mean**
Baseline IEPD	42	4.9	4-6	0.75	0.125
1 Month IEPD		1.58	1-2	0.50	0.083

Paired differences				
Mean	**Standard deviation**	**Standard error of mean**	**2-tail Sig.**	**95% confidence interval**
3.53	0.736	0.123	0.000	3.279, 3.777

Table 10.22 The IEPD data at baseline and after one month use of the Reliance device as well as the mean paired differences.

The null hypothesis states that the population mean difference should be zero. There was a statistically significant difference between the means of the two populations, therefore one can reject the null hypothesis (Table 10.22).

BASELINE VS 3 MONTHS IEPD

The null hypothesis was that the mean number of incontinence episodes per day at three months while using the device was equal in both groups.

Comparison of IEPD for the Reliance group at baseline and after 3 months (n=29)					
Variable	**No of pairs**	**Mean**	**Range**	**SD**	**SE of mean**
Baseline IEPD	29	4.8	4-6	0.66	0.131
3 Months IEPD		1.31	1-2	0.47	0.078

Paired differences				
Mean	**Standard deviation**	**Standard error of mean**	**2-tail Sig**	**95% confidence interval**
3.81	0.71	0.118	0.000	3.57, 4.08

Table 10.23 The IEPD data at baseline and after three months use of the device as well as the mean paired differences.

There was a statistically significant difference between the means of the two populations, therefore one can reject the null hypothesis (Table 10.23).

BASELINE VS 6 MONTHS IEPD

I also assessed if there was any difference in the degree of protection afforded by the Reliance device based on the number of incontinence episodes in the urinary diary at the end of the trial. The null hypothesis was that the mean number of incontinence episodes per day at six months while using the device was equal in both groups.

Comparison of IEPD for the Reliance group at baseline and after 6 months (n=31)					
Variable	**No of pairs**	**Mean**	**Range**	**SD**	**SE of mean**
Baseline IEPD	31	4.91	4-6	0.67	0.133
6 Months IEPD		1.33	1-2	0.48	0.080

Paired differences				
Mean	**Standard deviation**	**Standard error of mean**	**2-tail Sig**	**95% confidence interval**
3.78	0.89	0.15	0.000	3.474, 4.082

Table 10.24 The IEPD data at baseline and after six months use of the device as well as the mean paired differences.

There was a statistically significant difference between the means of the two populations, therefore one can reject the null hypothesis (Table 10.24).

CONTROL OF INCONTINENCE
(CHANGES IN INCONTINENCE EPISODES PER DAY)

Seventeen of the patients did not have six-month urinary diary data to assess the number of IEPD at the end of the study. Thus, the analysis includes 31 patients. The effectiveness (control of incontinence) as determined by the number of IEPD revealed a significant reduction in urine loss during device use at each period of assessment.

INDIVIDUAL PATIENT RESPONSES
(CHANGES IN INCONTINENCE EPISODES PER DAY)

The individual patient responses based on the changes in incontinence episodes per day after 1,3, and 6 months of Reliance Urinary Control Insert use are illustrated in table 10.25 and figures. The table also illustrates the per cent of individual responses categorised by degree of improvement at each visit based on the IEPD recorded in the diaries.

No subject was made worse with device use in either group.

The individual patient responses after 1,3, and 6 months of Reliance Insert use					
Visit	**"Dry"**	**"Sig. Improved"**	**"Mod. Improved"**	**"Slightly Improved"**	**"No change"**
1 month	0	15	21	6	0
3 months	0	19	10	0	0
6 months	0	20	11	0	0

Table 10.25 The number (percentage) of individual patient responses categorised as changes in incontinence episodes per day on the urinary diary. [Dry = no IEPD; significantly improved = 75% reduction in IEPD; moderately improved = 50% to 74% reduction in IEPD; slightly improved = 25% to 49% reduction in IEPD; no change = ± 25% change from baseline; worse = greater than 25% increase in IEPD].

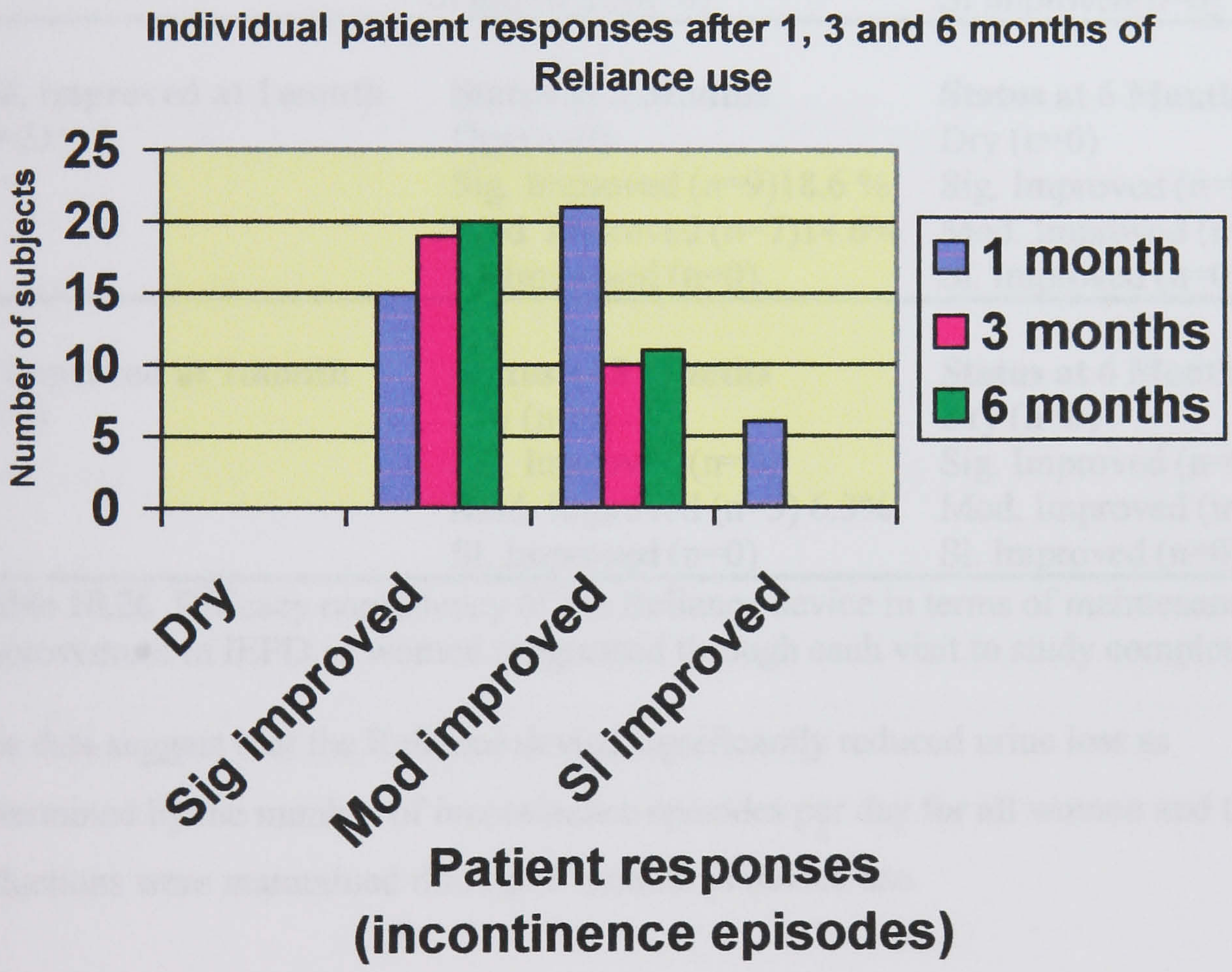


Figure 10.13 Individual patient responses categorised as changes in incontinence episodes per day on the urinary diary.

EFFICACY CONSISTENCY

(CHANGES IN INCONTINENCE EPISODES PER DAY)

As women progressed through each visit to completion, the consistency in improvement in the IEPD with device use was also determined (Table 10.26).

Efficacy consistency in terms of improvement in IEPD as women progressed through each visit to completion		
Sig. improved at 1 month (n=15)	**Status at 3 Months** Dry (n=0) Sig. Improved (n=10)20.8% Mod. Improved (n=0) Sl improved(n=0)	**Status at 6 Months** Dry (n=0) Sig. Improved (n=11)22.9% Mod. Improved (n=2)4.2% Sl improved(n=0)
Md. improved at 1month (n=21)	**Status at 3 Months** Dry (n=0) Sig. Improved (n=9)18.6 % Mod. Improved (n=7)14.6% Sl. Improved (n=0)	**Status at 6 Months** Dry (n=0) Sig. Improved (n=9)18.6% Mod. Improved (n=7)14.6% Sl. Improved (n=0)
Sl improved at 1month (n=6)	**Status at 3 Months** Dry (n=0) Sig. Improved (n=0) Mod. Improved (n=3) 6.3% Sl. Improved (n=0)	**Status at 6 Months** Dry (n=0) Sig. Improved (n=0) Mod. Improved (n=2)4.2% Sl. Improved (n=0)

Table 10.26 Efficacy consistency of the Reliance device in terms of maintenance of improvement in IEPD as women progressed through each visit to study completion.

The data suggest that the Reliance device significantly reduced urine loss as determined by the number of incontinence episodes per day for all women and these reductions were maintained through 6 months of device use.

DOMAIN OF CLINICIANS OBSERVATIONS
QUANTIFICATION OF URINE LOSS

RELIANCE GROUP

NUMBER OF CONTINENCE PADS USED OVER 5 DAYS

Similar comparisons of the mean number of continence pads used over 5 days while using a Reliance device at the one, three and six months visit assessments with that obtained at study inclusion is illustrated in table 10.27.

Comparison of the number of pads used over 5 days for the Reliance group at baseline and after each follow-up visit

Visit	No assessed	Mean no. of pads used	Range	SD
Baseline	48	10.6	8-12	1.23
1 Month	42	5.00	4-6	0.67
3 Months	29	3.62	3-5	0.72
6 Months	31	3.43	3-5	0.65

Table 10.27 Comparison of the mean number of continence pads used over 5 days recorded in the urinary diary while using a device at the one, three and six months visit assessments with that obtained at study inclusion.

BASELINE VS 1 MONTH PAD USE

Null Hypothesis

The means of the two populations, number of continence pads used over 5 days, at baseline and after application of the Reliance device at 1 month are the same (n = 42 pairs of observations). The table (10.28) shows the pad use data at baseline and after one-month use of the device.

Comparison of pad use data for the Reliance group at baseline and after 1 month (n=42)					
Variable	**No of pairs**	**Mean**	**Range**	**SD**	**SE of mean**
Baseline pad use	42	10.5	8-12	1.3	0.203
1 Month pad use		5.00	4-6	0.67	0.11

Paired differences				
Mean	**Standard deviation**	**Standard error of mean**	**2-tail Sig**	**95% confidence interval**
5.62	1.16	0.191	0.000	5.234, 6.01

Table 10.28 The continence pad use data at baseline and after one month use of the Reliance device as well as the mean paired differences.

The null hypothesis states that the population mean difference should be zero. There was a statistically significant difference in the means of the two populations, therefore one can reject the null hypotheses.

BASELINE VS 3 MONTHS PAD USE

Null Hypothesis

The means of the two populations, continence pad use at baseline and after application of the Reliance device at 3 months are the same (n =29 pairs of observations). The table shows the pad use data at baseline and after three months use of the device.

Comparison of pad use data for the Reliance group at baseline and after 3 months (n=29)					
Variable	**No of pairs**	**Mean**	**Range**	**SD**	**SE of mean**
Baseline pad use	29	10.3	8-12	1.33	0.223
3 Months pad use		3.62	3-5	0.72	0.118

Paired differences				
Mean	**Standard deviation**	**Standard error of mean**	**2-tail Sig**	**95% confidence interval**
7.00	1.53	0.251	0.000	6.491, 7.509

Table 10.29 The continence pad use data at baseline and after three months use of the device as well as the mean paired differences.

There was a statistically significant difference in the means of the two populations, therefore one can reject the null hypotheses (Table 10.29).

BASELINE VS 6 MONTHS PAD USE

Null Hypothesis

The means of the two populations, pad use at baseline and after application of the Reliance device at six months are the same (n = 31 pairs of observations). The table (10.30) shows the pad use data at baseline and after six months utilisation of the device.

Comparison of pad use data for the Reliance group at baseline and after 6 months (n=31)

Variable	No of pairs	Mean	Range	SD	SE of mean
Baseline pad use	31	10.	8-12	1.41	0.263
6 Months pad use		3.43	3-5	0.647	0.106

Paired differences				
Mean	**Standard deviation**	**Standard error of mean**	**2-tail Sig**	**95% confidence interval**
7.19	1.51	0.248	0.000	6.687, 7.692

Table 10.30 The pad usage data at baseline and after six months use of the device as well as the mean paired differences.

There was a statistically significant difference in the means of the two populations, therefore one can reject the null hypotheses.

CONTROL OF INCONTINENCE
(CHANGES IN CONTINENCE PAD UTILISATION)

Seventeen of the patients did not have six-month continence pad usage data available at the end of the study. Thus, the analysis includes 31 patients. The effectiveness (control of incontinence) as determined by incontinence pad usage revealed a significant reduction in urine loss during device use at each period of assessment.

INDIVIDUAL PATIENT RESPONSES
(CHANGES IN CONTINENCE PAD UTILISATION)

The individual patient responses based on the changes in continence pad utilisation after 1,3, and 6 months of Reliance Urinary Control Insert use are illustrated in table 10.31 and figure 10.14.

The individual patient responses after 1,3, and 6 months of Reliance insert use				
Visit	"Dry"	"Sig. Improved"	"No change"	"Worse"
1 month	0	32(66.7%)	10(20.8%)	0
3 months	0	29(60.4%)	0	0
6 months	0	31(64.6%)	0	0

Table 10.31 The number (percentage) of individual patient responses categorised by degree of improvement. ["Completely dry" = No pads used over 5 days of recordings; "significantly improved" = 50% reduction in pad usage; "no change" = ± 25% change from baseline; "worse" = greater than 25% increase from baseline pad usage]

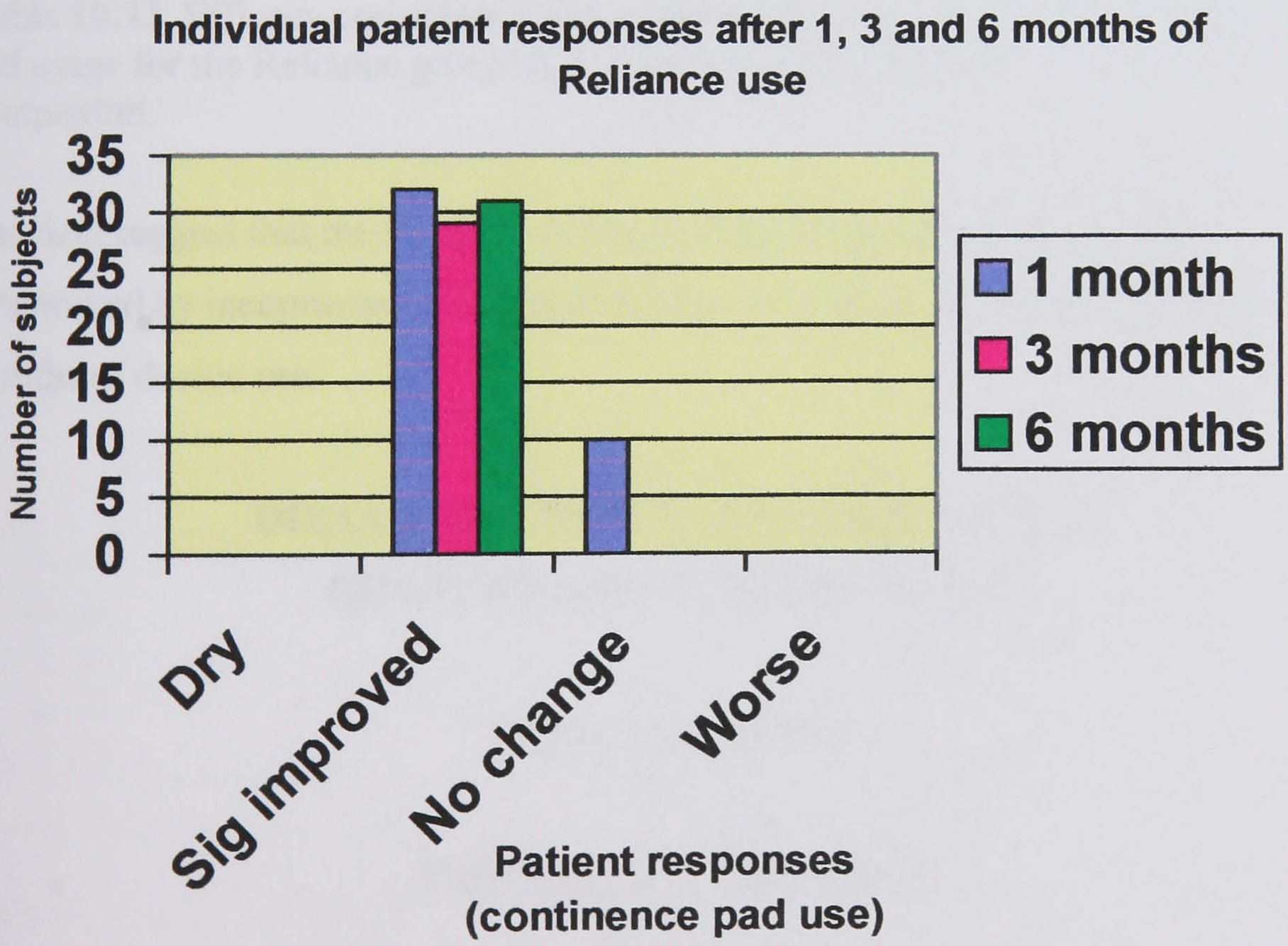


Figure 10.14 Individual patient responses categorised by degree of improvement over time in women using the Reliance device.

EFFICACY CONSISTENCY
(CHANGES IN CONTINENCE PAD UTILISATION)

Efficacy consistency as assessed by the maintenance in reduction in continence pad utilisation was also determined for the Reliance device as women progressed through each visit to completion (Table 10.32).

Efficacy consistency (pad use) for the Reliance device as women progressed through each visit to completion

Sig. improved at 1 month (n=32)	**Status at 3 Months** Dry (n=0) Sig. Improved (n=27)56.3% No change (n=0) 2 diaries missing	**Status at 6 Months** Dry (n=0) Sig. Improved (n=29)60.4% No change (n=0)
No change at 1 month (n=10)	**Status at 3 Months** Dry (n=0) Sig. Improved (n=2)4.2% No change (n=0)	**Status at 6 Months** Dry (n=0) Sig. Improved (n=2)4.2% No change (n=0)

Table 10.32 Efficacy consistency as determined by the maintenance of reduction in pad usage for the Reliance group as women progressed through each visit to study completion.

The data suggest that the Reliance device significantly reduced urine loss as determined by incontinence pad use and these reductions were maintained through 6 months of device use.

DOMAIN OF CLINICIANS OBSERVATIONS
QUANTIFICATION OF URINE LOSS

RELIANCE GROUP

PAD WEIGHT TEST DATA

The mean PWT gains while using a Reliance device at the one, three and six months visit assessments with that obtained at study inclusion is illustrated in table 10.33.

Comparison of PWT data for the Reliance group at baseline and after each follow-up visit				
Visit	No assessed	Mean PWT(g)	Range	SD
Baseline	48	31.2	1-99	32.1
1 Month	40	0.76	0-3.5	0.71
3 Months	29	0.93	0-4.6	0.93
6 Months	31	1.30	0.1-2.0	3.43

Table 10.33 Comparison of the mean PWT gains while using a device at the one, three and six months visit assessments with that obtained at study inclusion Note that of the 42 patients reviewed at one month, there was missing PWT data on two of the individuals who actually attended the visit.

Comparisons were made, for the Reliance group, of the PWT gains at baseline and at one, three and 6 months of device use.

BASELINE VS 1 MONTH PWT RESULTS

Null Hypothesis

The means of the two populations, PWT gains at baseline and after use of the Reliance device at one month are the same (n = 40 pairs of observations). Table 10.34 shows the PWT data at baseline and after one-month use of the device.

Comparison of PWT data for the Reliance group at baseline and after 1 month (n=42)				
Variable	No of pairs	Mean	SD	SE of mean
Baseline PWT(g)	40	32.64	33.81	5.35
1 Month PWT(g)		0.76	0.705	0.11

Paired differences				
Mean	**Standard deviation**	**Standard error of mean**	**2-tail Sig**	**95% confidence interval**
31.88	33.78	5.34	0.000	21.07, 42.68

Table 10.34 The PWT data at baseline and after one month use of the device as well as the mean paired differences.

The null hypothesis states that the population mean difference should be zero. There was a statistically significant difference in the means of the two populations, therefore one can reject the null hypotheses.

BASELINE VS 3 MONTHS PWT RESULTS

Null Hypothesis

The means of the two populations, PWT gains at baseline and after use of the Reliance device at three months are the same (n = 29 pairs of observations). Table 10.35 shows the PWT data at baseline and after three months use of the device.

Comparison of PWT data for the Reliance group At baseline and after 3 months (n=29)

Variable	No of pairs	Mean	SD	SE of mean
Baseline PWT(g)	29	35.26	38.05	7.07
3 Months PWT(g)		0.93	0.93	0.17

Paired differences				
Mean	**Standard deviation**	**Standard error of mean**	**2-tail Sig**	**95% confidence interval**
34.33	37.79	7.02	0.000	19.95, 48.71

Table 10.35 The PWT data at baseline and after three months use of the device as well as the mean paired differences.

There was a statistically significant difference in the means of the two populations, therefore one can reject the null hypotheses.

BASELINE VS 6 MONTHS PWT RESULTS

Null Hypothesis

The means of the two populations, PWT gains at baseline and after use of the Reliance device at six months are the same (n=31 pairs of observations). Table 10.36 shows the PWT data at baseline and after six months use of the device.

Comparison of PWT data for the Reliance group At baseline and after 6 months (n=31)				
Variable	**No of pairs**	**Mean**	**SD**	**SE of mean**
Baseline PWT(g)	31	33.77	36.94	6.63
6 Months PWT(g)		1.30	3.43	0.62

Paired differences				
Mean	**Standard deviation**	**Standard error of mean**	**2-tail Sig**	**95% confidence interval**
32.47	36.91	6.63	0.000	18.93, 46.01

Table 10.36 The PWT data at baseline and after six months use of the device as well as the mean paired differences.

There was a statistically significant difference in the means of the two populations, therefore one can reject the null hypotheses.

CONTROL OF INCONTINENCE
(CHANGE IN PAD WEIGHT TEST GAINS)

Seventeen of the patients did not have 6-month PWT data available at the end of the study. Thus, the PWT analysis includes 31 patients. The effectiveness (control of incontinence) as determined by pad weight testing revealed a significant reduction in urine loss during device use at each period of assessment.

INDIVIDUAL PATIENT RESPONSES
(CHANGE IN PAD WEIGHT TEST GAINS)

The categories of individual patient responses for the PWT gains were described in the chapter on methods of analysis but are repeated for convenience and are as follows: "completely dry" = 1g of urine or less on PWT gains; "significantly improved" = less than 2g in urine loss but not completely dry; "moderately improved" = between 2.1g and 3g in urine loss; "slightly improved" = between 3.1g and 4.9g in urine loss; "no change" = 5g or more in urine loss and "worse" = greater than 25% increase from baseline PWT gains.

The individual patient responses after 1,3, and 6 months of Reliance Urinary Control Insert use are illustrated in table 10.37 and figure 10.15.

The individual patient responses after 1,3, and 6 months of Reliance Insert use						
Visit	"Dry" (</=1.0g)	"Sig. Improved" (</=2g)	"Mod. Improved" 2.1–3g	"Slightly Improved" (3.1–4.9g)	"No change" (>/=5g)	"Worse" >25% of baseline
1 month	31(64.6%)	6(12.5%)	3(6.3%)	1(2%)	0	0
3 months	22(45.8%)	4(8.3%)	2(4.2%)	1(2%)	0	0
6 months	25(52.1)	3(6.3%)	2(4.2%)	0	0	0

Table 10.37 The number (percentage) of individual patient responses categorised by degree of improvement.

No subject was made worse as a consequence of device use in either group.

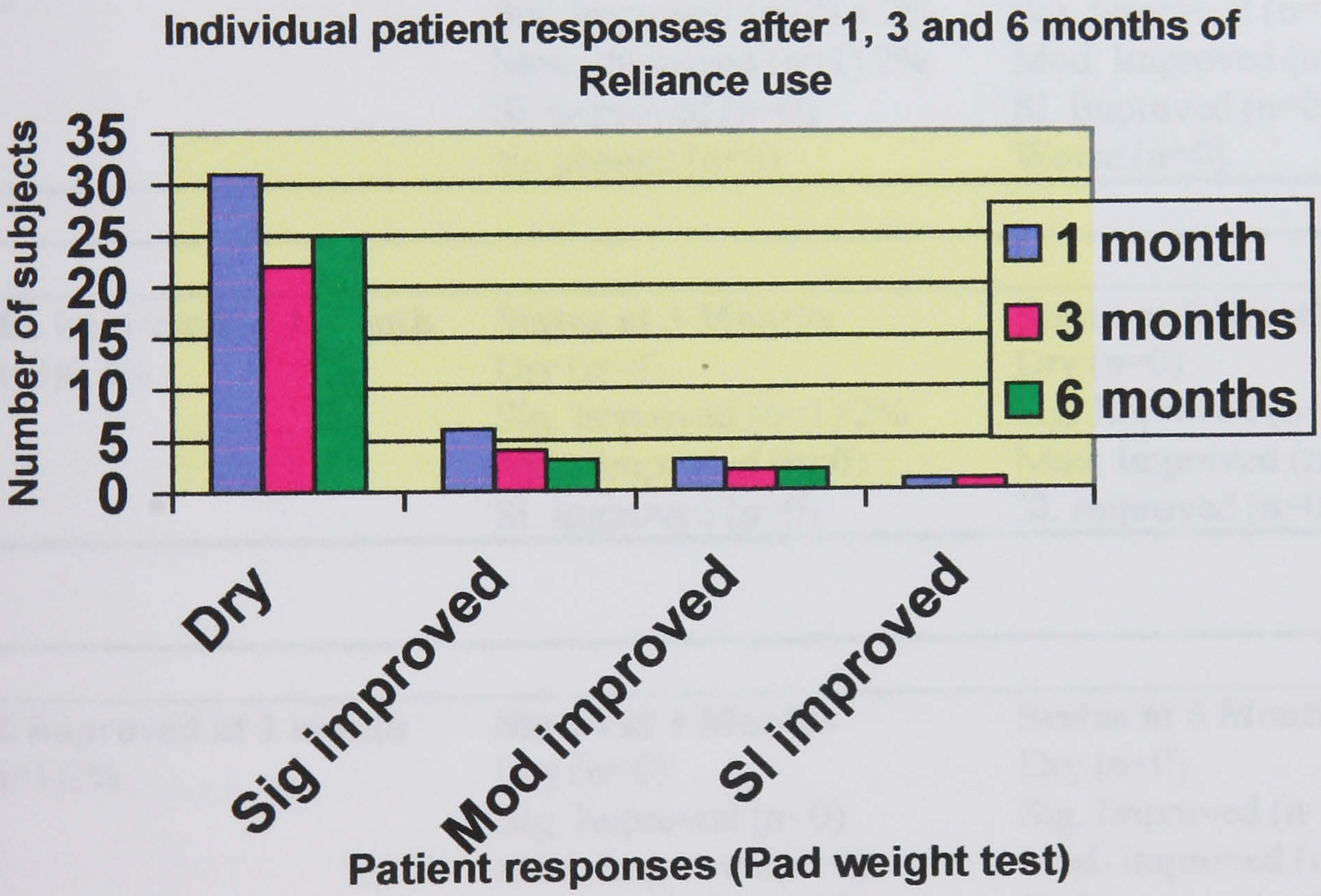


Figure 10.15 Individual patient responses categorised by degree of improvement based on pad weight tests.

EFFICACY CONSISTENCY
(CHANGE IN PAD WEIGHT TEST GAINS)

Efficacy consistency was also determined for the PWT data as women progressed through each visit to completion (Table 10.38).

Efficacy consistency for the PWT data as women progressed through each visit to completion		
Dry at 1 month (n=31)64.6%	**Status at 3 Months** Dry (n=20) 41.7% Sig. Improved (n=1) 2% Mod. Improved (n=1) 2% Sl. improved (n=1) 2%	**Status at 6 Months** Dry (n=20) 41.7% Sig. Improved (n=1) 2% Mod. Improved (n=2) 4.2% Sl. Improved (n=0)
Sig. improved at 1 month (n=6)12.5%	**Status at 3 Months** Dry (n=2) 4.2% Sig. Improved (n=2) 4.2% Mod. Improved (n=1) 2% Sl. improved (n=0) No change (n=0)	**Status at 6 Months** Dry (n=5)10.4% Sig. Improved (n=1) 2% Mod. Improved (n=0) Sl. Improved (n=0) Worse (n=0)
Md. improved at 1 month (n=3)6.3%	**Status at 3 Months** Dry (n=0) Sig. Improved (n=1) 2% Mod. Improved (n=0) Sl. improved (n=0)	**Status at 6 Months** Dry (n=0) Sig. Improved (n=1) 2% Mod. Improved (n=0) Sl. Improved (n=0)
Sl. improved at 1 month (n=1)2%	**Status at 3 Months** Dry (n=0) Sig. Improved (n=0) Mod. Improved (n=0) Sl. improved (n=1) 2%	**Status at 6 Months** Dry (n=0) Sig. Improved (n=0) Mod. Improved (n=0) Sl. Improved (n=1) 2%

Table 10.38 Representation of efficacy consistency for the PWT data as women progressed through each visit to study completion.

The data suggest that the Reliance device significantly reduced urine loss as determined by pad weighing tests and these reductions were maintained through 6 months of device use.

DOMAIN OF CLINICIANS OBSERVATIONS

QUANTIFICATION OF URINE LOSS

FEMASSIST GROUP

INCONTINENCE EPISODES PER DAY

Analysis of urinary leakage by the number of incontinence episodes per day was determined from the mean number of IEPD at each visit as recorded in the diaries (Table 10.39).

Comparison of IEPD for the FemAssist group at baseline and after each follow-up visit

Visit	No assessed	Mean IEPD	Range	SD
Baseline	53	5.04	4-8	0.9
1 Month	47	1.63	1-2	0.49
3 Months	41	2.05	1-3	0.63
6 Months	36	1.00	0-2	0.59

Table 10.39 Comparison of the mean number of IEPD while using the FemAssist device at the one, three and six months visit assessments with that obtained at study inclusion.

I assessed whether or not there was any difference in the degree of protection afforded by the FemAssist device as assessed by the number of IEPD on the urinary diary at baseline without a device and after one, three and six months while using the device.

BASELINE VS 1 MONTH IEPD

Null Hypothesis

The means of the two populations, incontinence episodes per day at baseline and at 1 month, are equal. Table 10.40 shows the mean IEPD recorded at baseline and after one months device use.

Comparison of IEPD for the FemAssist group At baseline and after 1 month (n=47)					
Variable	**No of pairs**	**Mean**	**Range**	**SD**	**SE of mean**
Baseline IEPD	47	5.04	4-7	0.9	0.14
1 Month IEPD		1.63	1-2	0.49	0.07

Paired differences				
Mean	**Standard deviation**	**Standard error of mean**	**2-tail Sig**	**95% confidence interval**
3.4	0.96	0.14	0.000	3.13, 3.69

Table 10.40 The IEPD data at baseline and after one month use of the device as well as the mean paired differences.

The null hypothesis states that the population mean difference should be zero. There was a statistically significant difference between the means of the two populations, therefore one can reject the null hypothesis.

BASELINE VS 3 MONTHS IEPD

The null hypothesis was that the mean number of incontinence episodes per day at three months while using the device was equal in both groups.

Comparison of IEPD for the FemAssist group at baseline and after 3 months (n=41)					
Variable	**No of pairs**	**Mean**	**Range**	**SD**	**SE of mean**
Baseline IEPD	41	4.97	4-7	0.82	0.13
3 Months IEPD		2.05	1-3	0.63	0.1

Paired differences				
Mean	**Standard deviation**	**Standard error of mean**	**2-tail Sig**	**95% confidence interval**
2.93	0.87	0.14	0.000	2.65, 3.20

Table 10.41 The IEPD data at baseline and after three months use of the device as well as and the mean paired differences.

There was a statistically significant difference between the means of the two populations, therefore one can reject the null hypothesis (Table 10.41).

BASELINE VS 6 MONTHS IEPD

I also assessed if there was any difference in the degree of protection afforded by the FemAssist device based on the number of incontinence episodes in the urinary diary at the end of the trial. The null hypothesis was that the mean number of incontinence episodes per day at six months while using the device was equal in both groups.

Comparison of IEPD for the FemAssist group at baseline and after 6 months (n=36)

Variable	No of pairs	Mean	Range	SD	SE of mean
Baseline IEPD	36	4.94	4-7	0.83	0.14
6 Months IEPD		1.00	0-2	0.59	0.098

Paired differences				
Mean	Standard deviation	Standard error of mean	2-tail Sig	95% confidence interval
3.94	1.01	0.17	0.000	3.6, 4.3

Table 10.42 The IEPD data at baseline and after six months use of the device as well as the mean paired differences.

There is a statistically significant difference between the means of the two populations, therefore one can reject the null hypothesis (Table 10.42).

INDIVIDUAL PATIENT RESPONSES (CHANGES IN INCONTINENCE EPISODES PER DAY)

The individual patient responses after 1,3, and 6 months of FemAssist use are illustrated in table 10.43. The table also illustrates the per cent of individual responses categorised by degree of improvement at each visit based on the IEPD recorded in the diaries.

The individual patient responses after 1,3, and 6 months of FemAssist use (n=53)						
Visit	"Dry"	"Sig. Improved"	"Mod. Improved"	"Slightly Improved"	"No change"	"Worse"
1 month	0	9(17%)	20(37.7%)	7(13.2%)	11(20.8%)	0
3 months	0	2(3.8%)	19(35.8%)	13(24.5%)	7(13.2%)	0
6 months	6	18(34%)	11(20.8%)	1(1.9%)	0	0

Table 10.43 The number (percentage) of individual patient responses categorised by degree of improvement.

Individual patient responses on the five-day urinary diary revealed a large number of women categorised as dry or significantly improved based on the number of incontinence episodes per day (Figure 10.16).

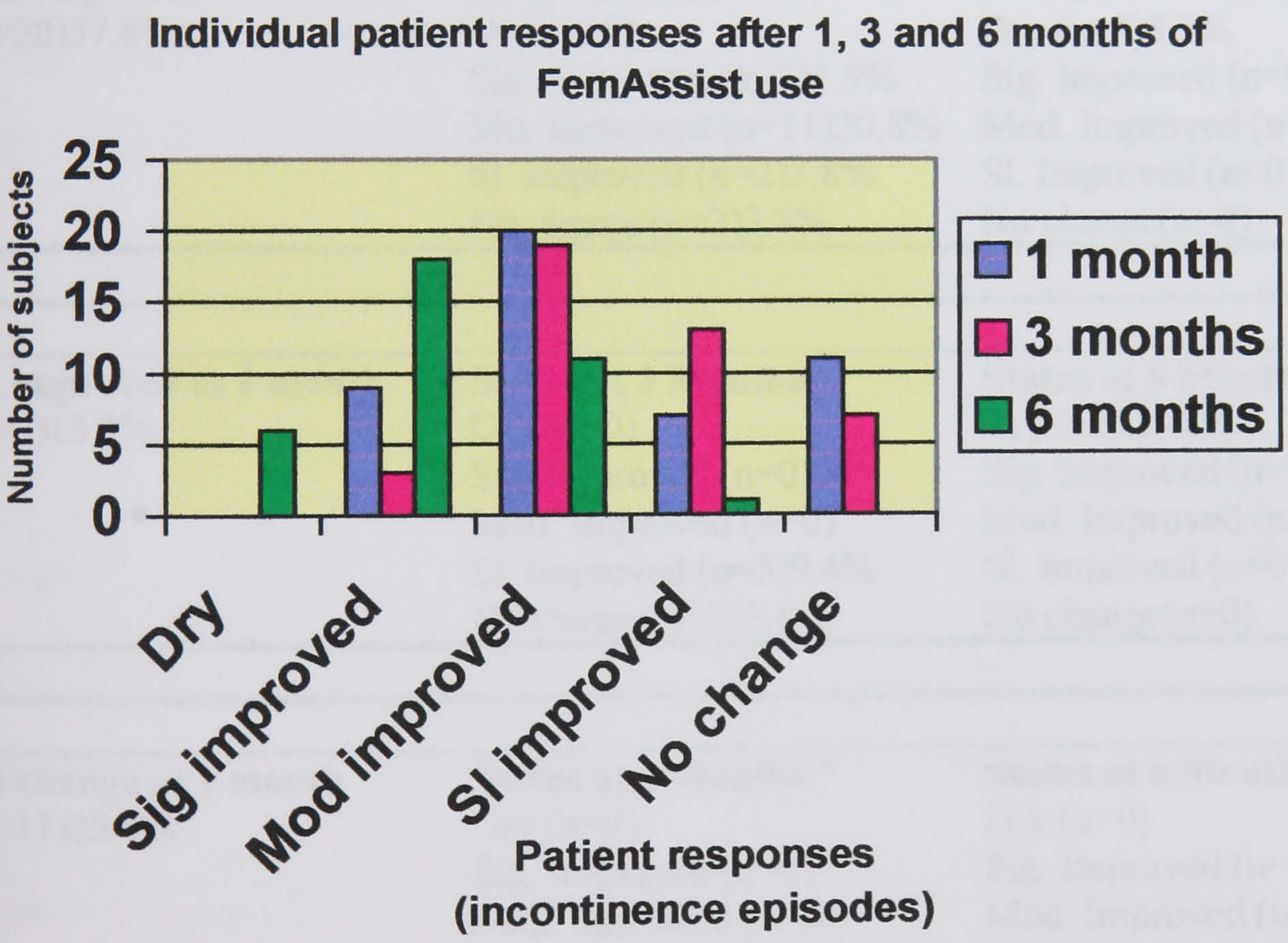


Figure 10.16 Individual patient responses on the five-day urinary diary in women using the Reliance device.

EFFICACY CONSISTENCY
(CHANGES IN INCONTINENCE EPISODES PER DAY)

As women progressed through each visit to completion, the consistency in improvement in the IEPD with device use was also determined (Table 10.44).

Efficacy consistency in terms of improvement in IEPD as women progressed through each visit to completion		
Sig. improved at 1 month (n=9)17%	**Status at 3 Months** Dry (n=0) Sig. Improved (n=1)1.9% Mod. Improved (n=8)15.1% Sl. improved (n=0)	**Status at 6 Months** Dry (n=1)1.9% Sig. Improved (n=8)15.1% Mod. Improved (n=0) Sl. Improved (n=0)
Md. improved at 1 month (n=20)37.8%	**Status at 3 Months** Dry (n=0) Sig. Improved (n=1)1.9% Md. Improved (n=11)20.8% Sl. improved (n=2)3.8% No change(n=2)3.8%	**Status at 6 Months** Dry (n=3)5.7% Sig. Improved (n=9)17% Mod. Improved (n=6)11.3% Sl. Improved (n=0) No change(n=0)
Sl. improved at 1 month (n=7)13.2%	**Status at 3 Months** Dry (n=0) Sig. Improved (n=0) Mod. Improved (n=0) Sl. improved (n=5)9.4% No change(n=2)3.8%	**Status at 6 Months** Dry (n=2)3.8% Sig. Improved (n=1)1.9% Mod. Improved (n=4)7.5% Sl. Improved (n=0) No change(n=0)
No change at 1 month (n=11)20.6%	**Status at 3 Months *** Dry (n=0) Sig. Improved (n=0) Mod. Improved (n=0) Sl. improved (n=6)11.3% No change(n=3)5.7%	**Status at 6 Months** Dry (n=0) Sig. Improved (n=0) Mod. Improved (n=1)1.9% Sl. Improved (n=1)1.9% No change(n=0)

Table 10.44 Efficacy consistency of the FemAssist device in terms of maintenance of improvement in IEPD as women progressed through each visit to study completion.
*= Two diaries were not available for evaluation at 3 months.

Twenty women were moderately improved at 1 month. When followed up at 3 months, two were lost to follow-up and two women reviewed did not complete diaries. Eleven women were unchanged at one month. When followed up at 3

months, 2 were lost and when reviewed at 6 months, a further 7 were lost to follow-up.

The data suggest that the FemAssist device significantly reduced urine loss as determined by the number of incontinence episodes per day for all women and these reductions were maintained through 6 months of device use.

DOMAIN OF CLINICIANS OBSERVATIONS

QUANTIFICATION OF URINE LOSS

FEMASSIST GROUP

NUMBER OF CONTINENCE PADS USED OVER 5 DAYS

The mean number of continence pads used over five days while using a FemAssist device at the one, three and six months visit assessments with that obtained at study inclusion is illustrated in table 10.45.

Comparison of the number of pads used over 5 days for the FemAssist group at baseline and after each follow-up visit

Visit	No assessed	Mean no. of pads used	Range	SD
Baseline	53	11.2	8-15	1.68
1 Month	47	5.75	5-9	0.91
3 Months	41	4.61	4-5	0.49
6 Months	36	4.33	4-5	0.48

Table 10.45 Comparison of the mean number of continence pads used over five days recorded in the urinary diary while using a FemAssist device at the one, three and six months visit assessments with that obtained at study inclusion.

Similar comparisons were made, for the FemAssist group, of the differences in the mean number of continence pads used over five days at baseline and at one, three and six months of device use.

BASELINE VS 1 MONTH PAD USE

Null Hypothesis

The means of the two populations, number of pads used over 5 days, at baseline and after application of the FemAssist device at one month are the same (n = 47 pairs of observations). Table 10.46 shows the pad use data at baseline and after one-month use of the device.

Comparison of pad use data for the FemAssist group at baseline and after 1 month (n=47)					
Variable	**No of pairs**	**Mean**	**Range**	**SD**	**SE of mean**
Baseline pad use	47	11.2	8-15	1.68	0.25
1 Month pad use		5.78	5-9	0.9	0.13

Paired differences				
Mean	**Standard deviation**	**Standard error of mean**	**2-tail Sig**	**95% confidence interval**
5.4	1.84	0.3	0.000	4.67, 5.96

Table 10.46 The pad use data at baseline and after one-month use of the FemAssist device as well as the mean paired differences.

The null hypothesis states that the population mean difference should be zero. There was a statistically significant difference in the means of the two populations, therefore one can reject the null hypotheses.

BASELINE VS 3 MONTHS PAD USE

Null Hypothesis

The means of the two populations, pad use at baseline and after use of the FemAssist device at three months are the same (n=41 pairs of observations). Table 10.47 shows the pad use data at baseline and after three months use of the device.

Comparison of pad use data for the FemAssist group at baseline and after 3 months (n=41)					
Variable	**No of pairs**	**Mean**	**Range**	**SD**	**SE of mean**
Baseline pad use	41	11.2	8-15	1.76	0.28
3 Months pad use		4.6	4-5	0.5	0.08

Paired differences				
Mean	**Standard deviation**	**Standard error of mean**	**2-tail Sig**	**95% confidence interval**
6.6	1.86	0.3	0.000	6.02, 7.22

Table 10.47 The pad use data at baseline and after three months use of the FemAssist device as well as the mean paired differences.

There was a statistically significant difference in the means of the two populations, therefore one can reject the null hypotheses.

BASELINE VS 6 MONTH PAD USE

Null Hypothesis

The means of the two populations, pad use at baseline and after application of the FemAssist device at six months are the same (n=36 pairs of observations). Table 10.48 shows the pad use data at baseline and after six-month use of the device.

Comparison of pad use data for the FemAssist group at baseline and after 6 months (n=36)					
Variable	**No of pairs**	**Mean**	**Range**	**SD**	**SE of mean**
Baseline pad use	36	11.4	8-15	1.7	0.3
6 Months pad use		4.35	4-5	0.48	0.08

Paired differences				
Mean	**Standard deviation**	**Standard error of mean**	**2-tail Sig**	**95% confidence interval**
7.05	1.76	0.3	0.000	6.4, 7.67

Table 10.48 The pad usage data at baseline and after six months use of the FemAssist device as well as the mean paired differences.

There was a statistically significant difference in the means of the two populations, therefore one can reject the null hypotheses.

CONTROL OF INCONTINENCE
(CHANGES IN CONTINENCE PAD UTILISATION)

Seventeen of the patients did not have 6 month pad usage data available at the end of the study. Thus, the analysis includes 36 patients. The effectiveness (control of incontinence) as determined by incontinence pad usage revealed a significant reduction in urine loss during device use at each period of assessment.

INDIVIDUAL PATIENT RESPONSES
(CHANGES IN CONTINENCE PAD UTILISATION)

The individual patient responses based on the changes in continence pad utilisation after 1,3, and 6 months of FemAssist use are illustrated in table 10.49 and figure 10.17.

The individual patient responses after 1,3, and 6 months of FemAssist device use			
Visit	"Dry"	"Sig. Improved"	"No change"
1 month	0	13(24.5%)	34(64.2%)
3 months	0	39(73.6%)	2(3.8%)
6 months	0	34(64.2%)	2(3.8%)

Table 10.49 The number (percentage) of individual patient responses categorised by degree of improvement.

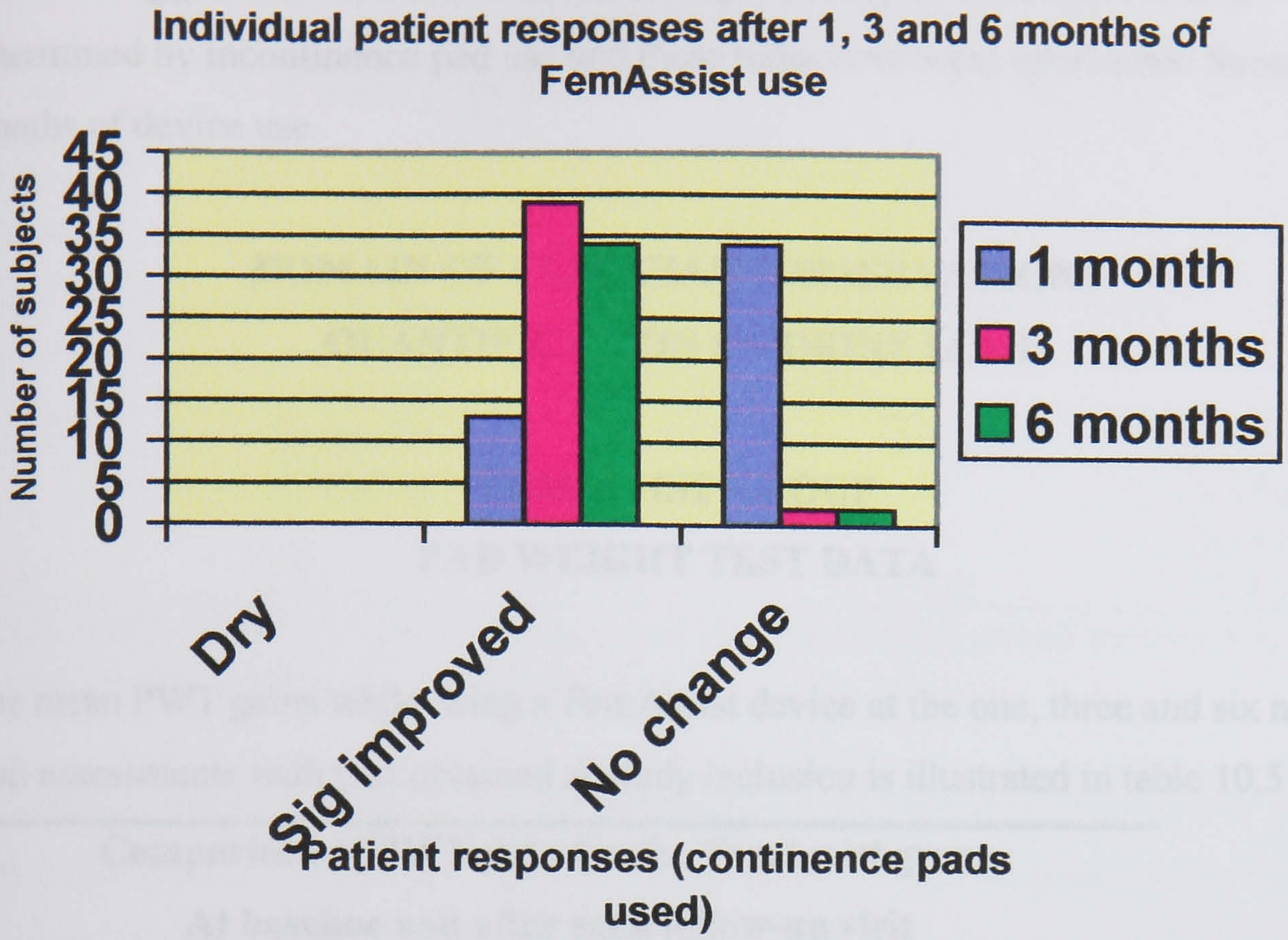


Figure 10.17 Individual patient responses categorised by degree of improvement in the number of continence pads used in the FemAssist group.

EFFICACY CONSISTENCY

(CHANGES IN CONTINENCE PAD UTILISATION)

Efficacy consistency was also determined for the FemAssist device as women progressed through each visit to completion (Table 10.50).

Efficacy consistency (pad use) for the FemAssist device as women progressed through each visit to completion		
Sig. improved at 1 month (n=13)	**Status at 3 Months***	**Status at 6 Months**
	Dry (n=0)	Dry (n=0)
	Sig. Improved (n=11)20.8%	Sig. Improved (n=9)17%
	No change (n=0)	No change (n=2)3.8%
* = 2 drop out at 3 months		

No change at 1 month (n=34)	**Status at 3 Months**	**Status at 6 Months**
	Dry (n=0)	Dry (n=0)
	Sig. Improved (n=28)52.8%	Sig. Improved (n=25)47.2%
	No change (n=2)3.8%	No change (n=0)

** = 4 drop out at 3 months and a further 5 at 6 months

Table 10.50 Efficacy consistency as determined by the maintenance of reduction in pad usage for the FemAssist group as women progressed through each visit to study completion.

The data suggest that the FemAssist device significantly reduced urine loss as determined by incontinence pad use and these reductions were maintained through 6 months of device use.

DOMAIN OF CLINICIANS OBSERVATIONS

QUANTIFICATION OF URINE LOSS

FEMASSIST GROUP

PAD WEIGHT TEST DATA

The mean PWT gains while using a FemAssist device at the one, three and six months visit assessments with that obtained at study inclusion is illustrated in table 10.51

Comparison of PWT data for the FemAssist group

At baseline and after each follow-up visit

Visit	**No assessed**	**Mean PWT(g)**	**Range**	**SD**
Baseline	53	28.7	1.1-128	23.7
1 Month	47	3.27	0.5-6	1.06
3 Months	41	3.44	2-6	0.94
6 Months	36	3.61	2-5	0.65

Table 10.51 Comparison of the mean PWT gains while using a FemAssist device at the one, three and six months visit assessments with that obtained at study inclusion.

To determine if there were any differences in the mean PWT gains at each visit as a consequence of device use, comparisons were made, for the FemAssist group, of the PWT gains at baseline and at one, three and six months of device use.

BASELINE VS 1 MONTH PWT RESULTS

Null Hypothesis

The means of the two populations, PWT gains at baseline and after application of the FemAssist device at one month are the same (n = 47 pairs of observations). Table 10.52 shows the PWT data at baseline and after one-month use of the device.

Comparison of PWT data for the FemAssist group at baseline and after 1 month (n=47)				
Variable	**No of pairs**	**Mean**	**SD**	**SE of mean**
Baseline PWT(g)	47	28.7	23.7	3.45
1 Month PWT(g)		3.28	1.09	0.16

Paired differences				
Mean	**Standard deviation**	**Standard error of mean**	**2-tail Sig**	**95% confidence interval**
25.4	24	3.5	0.000	18.37, 32.5

Table 10.52 The PWT data at baseline and after one month use of the FemAssist device as well as the mean paired differences.

The null hypothesis states that the population mean difference should be zero. There was a statistically significant difference in the means of the two populations, therefore one can reject the null hypotheses.

BASELINE VS 3 MONTH PWT RESULTS

Null Hypothesis

The means of the two populations, PWT gains at baseline and after application of the FemAssist device at three months are the same (n = 41 pairs of observations). Table 10.53 shows the PWT data at baseline and after three months use of the device.

Comparison of PWT data for the FemAssist group at baseline and after 3 months (n=41)				
Variable	**No of pairs**	**Mean**	**SD**	**SE of mean**
Baseline PWT(g)	41	28.6	25.3	3.9
3 Months PWT(g)		3.43	0.94	0.14

Paired differences				
Mean	**Standard deviation**	**Standard error of mean**	**2-tail Sig**	**95% confidence interval**
25.25	25.54	4.0	0.000	17.1, 33.3

Table 10.53 The PWT data at baseline and after three months use of the FemAssist device as well as the mean paired differences.

There was a statistically significant difference in the means of the two populations, therefore one can reject the null hypotheses.

BASELINE VS 6 MONTH PWT RESULTS

Null Hypothesis

The means of the two populations, PWT gains at baseline and after application of the FemAssist device at six months are the same (n = 36 pairs of observations). Table 10.54 shows the PWT data at baseline and after six months use of the device.

Comparison of PWT data for the FemAssist group at baseline and after 6 months (n=36)				
Variable	**No of pairs**	**Mean**	**SD**	**SE of mean**
Baseline PWT(g)	36	29.66	26.17	4.3
6 Months PWT(g)		3.63	0.7	0.12

Paired differences				
Mean	**Standard deviation**	**Standard error of mean**	**2-tail Sig**	**95% confidence interval**
26.04	26.3	4.3	0.000	17.14, 33.9

Table 10.54 The PWT data at baseline and after six months use of the device as well as the mean paired differences.

There was a statistically significant difference in the means of the two populations, therefore one can reject the null hypotheses.

CONTROL OF INCONTINENCE
(CHANGE IN PAD WEIGHT TEST GAINS)

Seventeen of the patients did not have six-month PWT data available at the end of the study. Thus, the PWT analysis includes 36 patients. The effectiveness (control of incontinence) as determined by pad weight testing revealed a significant reduction in urine loss during device use at each period of assessment.

INDIVIDUAL PATIENT RESPONSES
(CHANGE IN PAD WEIGHT TEST GAINS)

The individual patient responses based on the changes in pad weight test gains after 1,3, and 6 months of FemAssist device use are illustrated in table 10.55 and figure 10.18.

The individual patient responses after 1,3, and 6 months of FemAssist use						
Visit	"Dry" (</=1.0g)	"Sig. Improved" (</=2g)	"Mod. Improved" (2.1–3g)	"Slightly Improved" (3.1–4.9g)	"No change" (>/=5g)	"Worse" >25% of baseline
1 month	1(1.9%)	2(3.8%)	20(37.7%)	16(30.2%)	8(15.1%)	0
3 months	0	9(17%)	6(11.3%)	25(47.2%)	1(1.9%)	0
6 months	0	1(1.9%)	9(17%)	24(45.3%)	2(3.8%)	0

Table 10.55 The number (percentage) of individual patient responses categorised by degree of improvement.

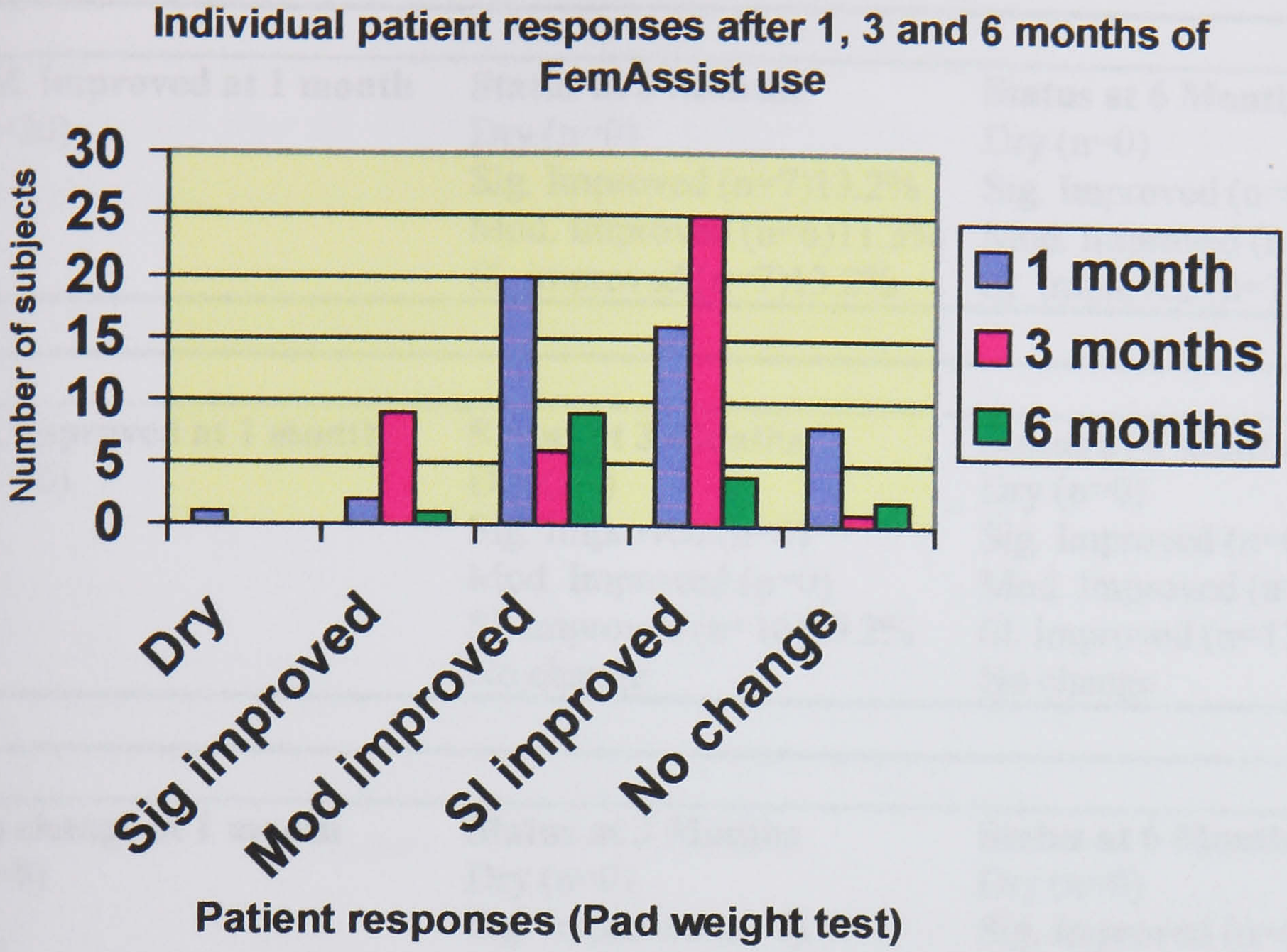


Figure 10.18 Individual patient responses categorised by degree of improvement based on the pad test in the FemAssist group.

EFFICACY CONSISTENCY
(CHANGE IN PAD WEIGHT TEST GAINS)

Efficacy consistency was also determined for the PWT data as women progressed through each visit to completion (Table 10.56).

Efficacy consistency for the PWT data as women progressed through each visit to completion		
Dry at 1 month (n=1)	**Status at 3 Months** Dropped out	**Status at 6 Months** Dropped out
Sig. improved at 1 month (n=2)	**Status at 3 Months** Dry (n=0) Sig. Improved (n=2)3.8% Mod. Improved (n=0) Sl. improved (n=0)	**Status at 6 Months** Dry (n=1)1.9% Sig. Improved (n=1)1.9% Mod. Improved (n=0) Sl. Improved (n=0)

Md. improved at 1 month (n=20)	**Status at 3 Months** Dry (n=0) Sig. Improved (n=7)13.2% Mod. Improved (n=6)11.3% Sl. improved (n=7)13.2%	**Status at 6 Months** Dry (n=0) Sig. Improved (n=0) Mod. Improved (n=6)11.3% Sl. Improved (n=7)13.2%
Sl. improved at 1 month (n=16)	**Status at 3 Months** Dry (n=) Sig. Improved (n=0) Mod. Improved (n=0) Sl. improved (n=16)30.2% No change	**Status at 6 Months** Dry (n=0) Sig. Improved (n=0) Mod. Improved (n=3)5.7% Sl. improved (n=13)24.5% No change
No change at 1 month (n=8)	**Status at 3 Months** Dry (n=0) Sig. Improved (n=0) Mod. Improved (n=0) Sl. improved (n=2)3.8% No change(n=1)1.9%	**Status at 6 Months** Dry (n=0) Sig. Improved (n=0) Mod. Improved (n=0) Sl. improved (n=4)7.5% No change(n=2)3.8%

Table 10.56 Representation of efficacy consistency for the PWT data as women progressed through each visit to study completion.

Twenty women were moderately improved at 1 month but following their 3-month visit, 7 dropped out. Eight women experienced no change at 1 month. When reviewed at 3 months, 2 had been lost to follow-up and 3 had missing diaries. However the latter were followed up at 6 months and had complete diaries then. The data suggest that the FemAssist device also significantly reduced urine loss as determined by pad weighing tests for all women and these reductions were maintained through 6 months of device use.

CHANGES IN URETHRAL FUNCTION AS A CONSEQUENCE OF DEVICE USE

RELIANCE GROUP

Possible changes in urethral function as a result of Reliance device use were evaluated by comparing PWT gains at the start and end of the trial assessed without a device in-situ. {Missing data = 17 (35.4%) patients.}

Null Hypothesis: The mean difference of the two populations, PWT gains before and after a period of 6 months device use is the same. The table illustrates the PWT gains at baseline and after six months use of the Reliance device as well as and the mean paired differences (table 10.57)

Comparison of PWT data for the Reliance group (without a device) at baseline and after 6 month (n=31)

Variable	No of pairs	Mean	SD	SE of mean
Baseline PWT(g)	31	33.8	36.9	6.635
6 Months PWT (g)		27.3	22.7	4.07

Paired differences				
Mean	**Standard deviation**	**Standard error of mean**	**2-tail Sig**	**95% confidence interval**
6.44	34.67	6.23	0.31	-6.28, 19.15

Table 10.57 The PWT gains at baseline and after six months use of the Reliance device as well as the mean paired differences to determine possible changes in urethral function.

The urine loss without the Reliance insert decreased from a mean of 33.8 grams at baseline; to 27.3 grams at 6 months, although this result was not statistically significant ($p>0.05$). The means of the two populations were the same so one can accept the null hypotheses.

FEMASSIST GROUP

Possible changes in urethral function as a result of FemAssist device use were similarly evaluated by comparing PWT gains at the start and end of the trial assessed without a device in-situ. {Missing data = 17 (32.1%) patients.}

Null Hypothesis

The mean difference of the two populations, PWT gains before and after a period of six months device use is the same. The table illustrates the PWT gains at baseline and after six months use of the FemAssist device as well as and the mean paired differences (table 10.58)

Comparison of PWT data for the FemAssist group (without a device) at baseline and after 6 month (n=36)				
Variable	**No of pairs**	**Mean**	**SD**	**SE of mean**
Baseline PWT(g)	36	29.7	29.27	5.26
6 Months PWT (g)		27.3	22.66	4.07

Paired differences				
Mean	**Standard deviation**	**Standard error of mean**	**2-tail Sig**	**95% confidence interval**
2.37	36.28	6.51	0.72	-10.93, 15.68

Table 10.58 The PWT gains at baseline and after six months use of the FemAssist device as well as the mean paired differences to determine possible changes in urethral function.

The urine loss without the insert decreased from a mean of 29.7 grams at baseline; to 27.3 grams at 6 months, although this result was not statistically significant ($p>0.05$). The means of the two populations were the same so one can accept the null hypotheses.

Women with moderate GSI responded much the same to device use overall compared to women with greater severity of urinary leakage.

FURTHER COMPARISON OF DEVICE GROUPS

RELIANCE Vs FEMASSIST

Inter group analysis was performed, comparing the number of incontinence episodes per day, the number of continence pads used over five days and the PWT gains obtained with each device, at each period of assessment. The two groups, Reliance users and FemAssist users were evaluated using the non-parametric Wilcoxon rank sum test for two independent populations. The Null hypothesis was that the medians of the two independent populations, Reliance group and FemAssist group, were equal for each of the continuous variables and sample sizes studied.

PAD TEST WEIGHT DATA
FEMASSIST VS RELIANCE

Assessment was made of whether or not there was any difference in the degree of protection afforded by each device in the two groups as evaluated on the PWT gains at 1,3 and 6 months (Tables 10.59 – 10.61).

Pad weight test data for Reliance and FemAssist users
At 1 month

	MIN	MAX	MEDIAN	Paired differences p-value
Reliance n=42	0	3.5	0.76	0.000
FemAssist n=47	0.5	6	3.28	

Table 10.59 The Pad weight test gains of the women in each group at 1 month follow-up assessment.

Pad weight test data for Reliance and FemAssist users
at 3 months

	MIN	MAX	MEDIAN	Paired differences p-value
Reliance n=29	0	4.6	0.93	0.000
FemAssist n=41	2	6	3.43	

Table 10.60 The Pad weight test gains of the women in each group at 3 months follow-up assessment.

Pad weight test data for Reliance and FemAssist users
at 6 months

	MIN	MAX	MEDIAN	Paired differences p-value
Reliance n=31	0.1	2	1.3	0.000
FemAssist n=36	2	5	3.62	

Table 10.61 The Pad weight test gains of the women in each group at 6 months follow-up assessment.

INDIVIDUAL PATIENT RESPONSES
(CHANGES IN PAD WEIGHT TEST GAINS)

The following data illustrates the proportion of women with GSI who were made dry or improved with use of a device based on the individual patient responses obtained from the PWT gains after 1,3, and 6 months of FemAssist and Reliance device use.

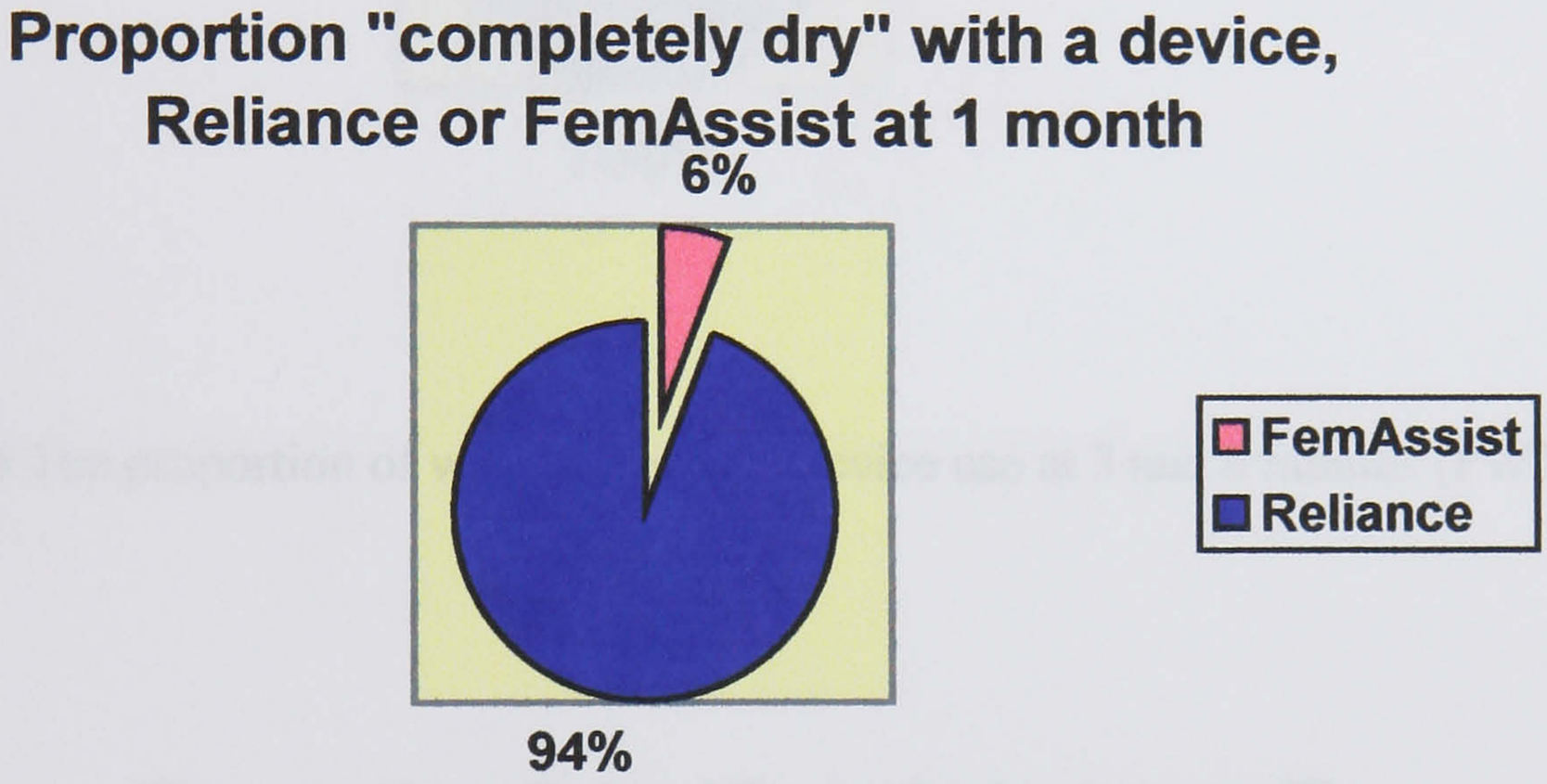


Figure 10.19 The proportion of women dry with device use at one month (PWT).

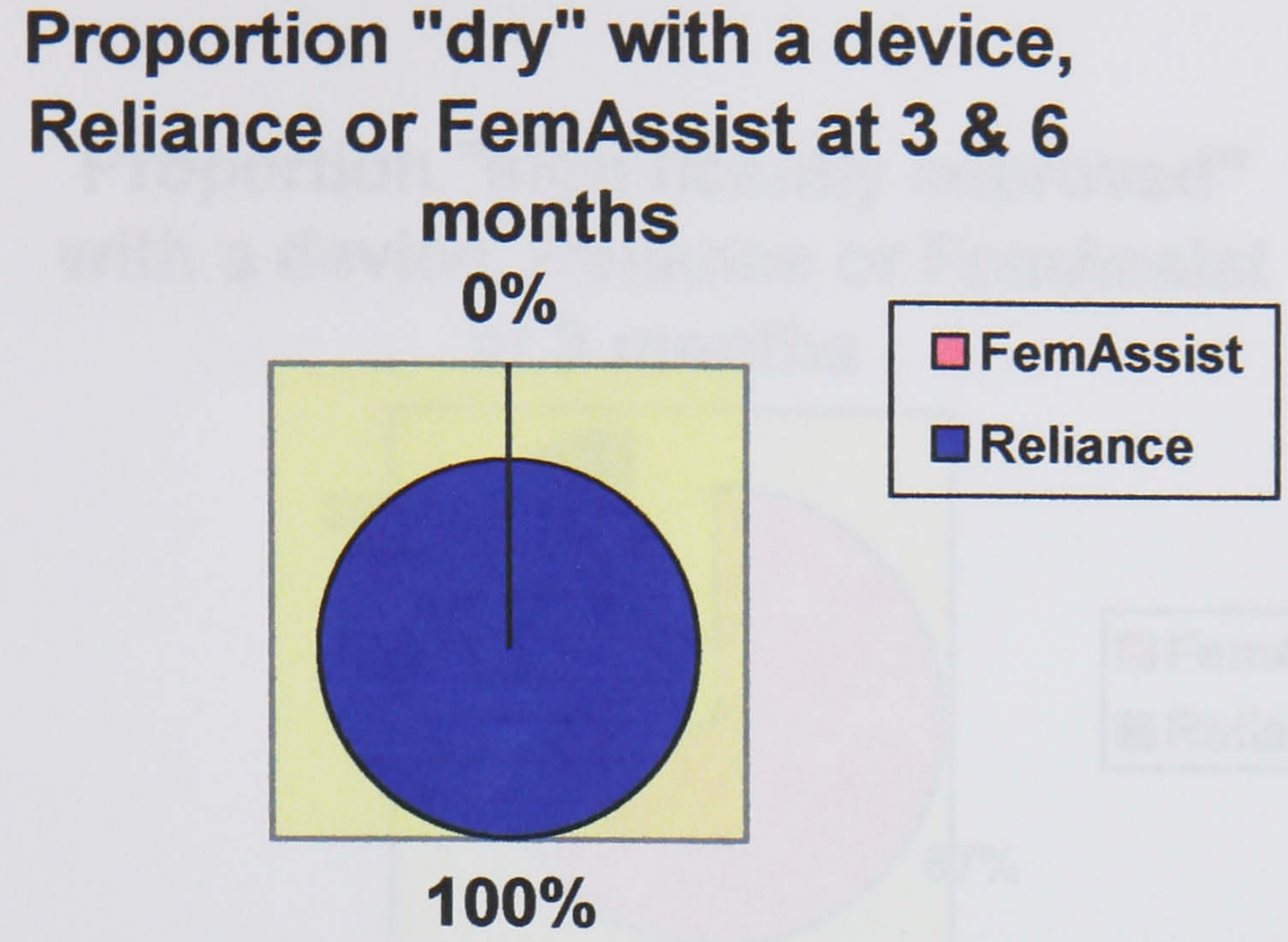


Figure 10.20 The proportion of women dry with device use at 3 and 6 months (PWT).

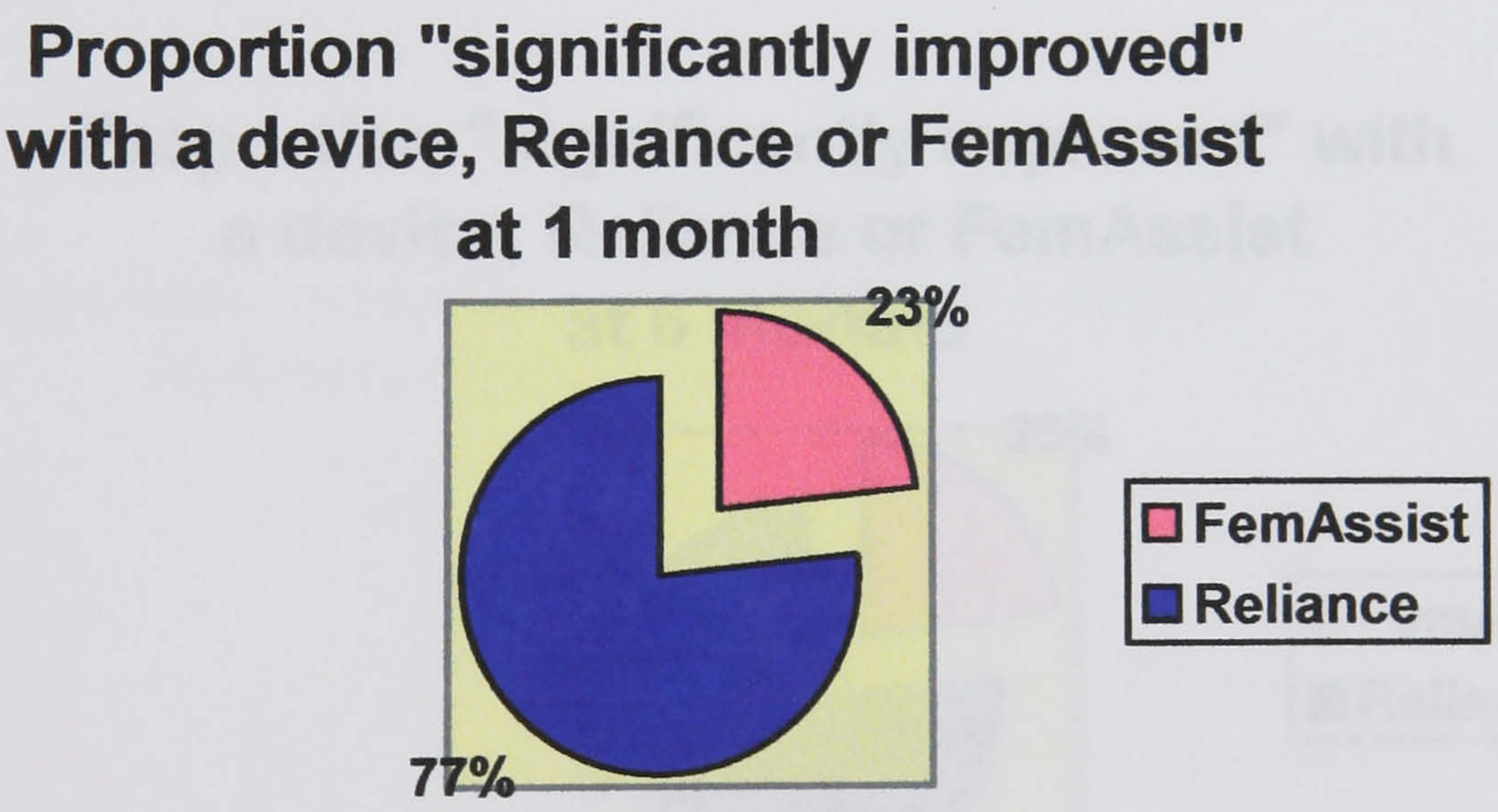


Figure 10.21 The proportion of women significantly improved with device use at one month (PWT).

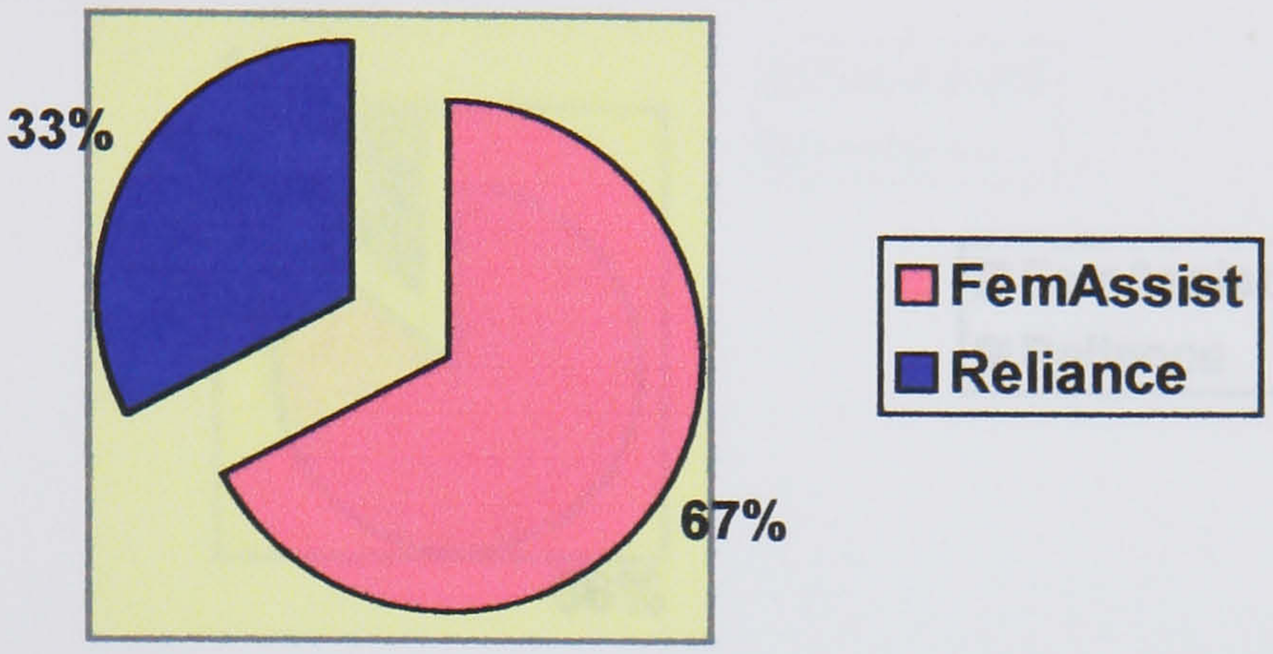


Figure 10.22 The proportion of women significantly improved with device use at 3 months (PWT).

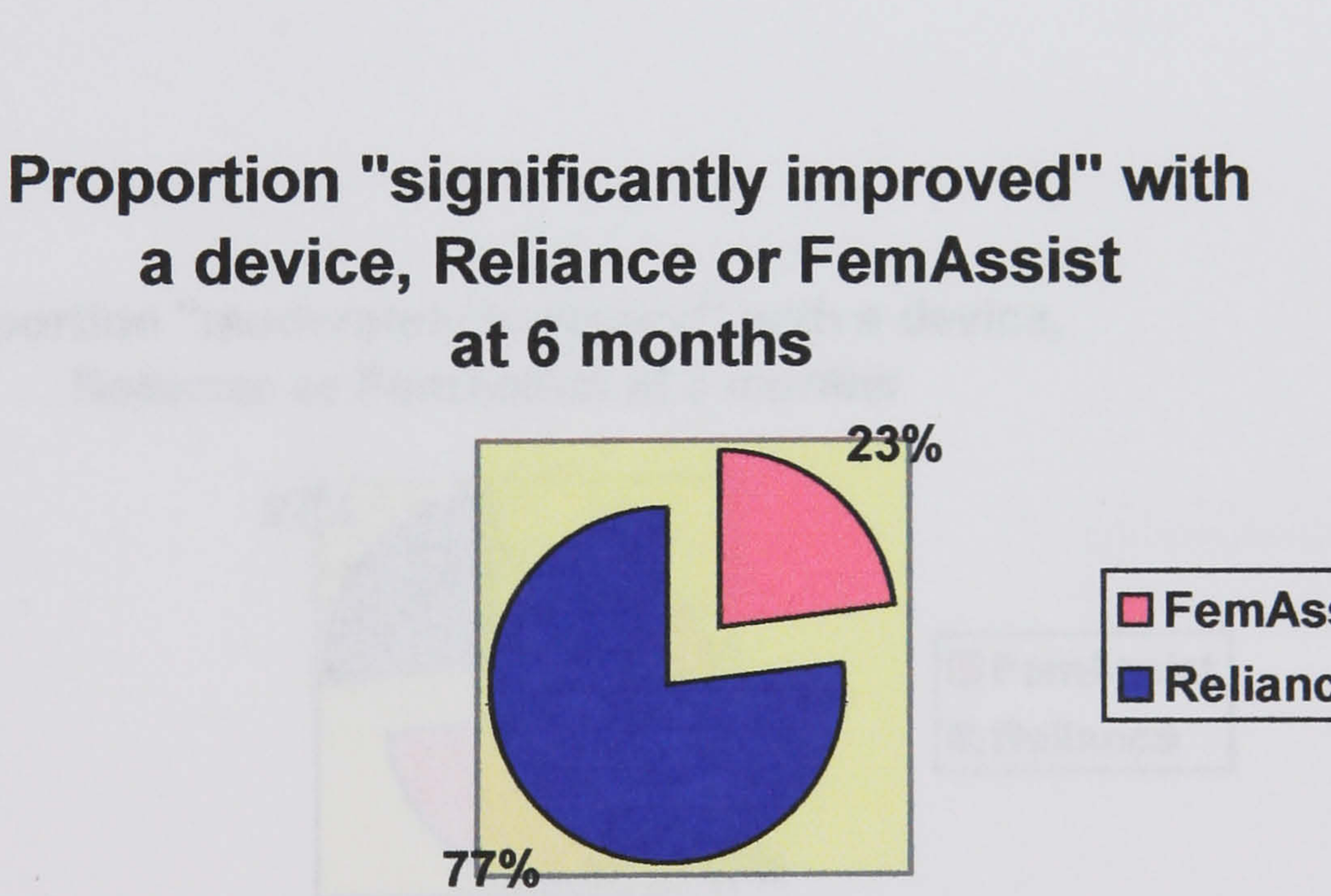


Figure 10.23 The proportion of women significantly improved with device use at 6 months (PWT).

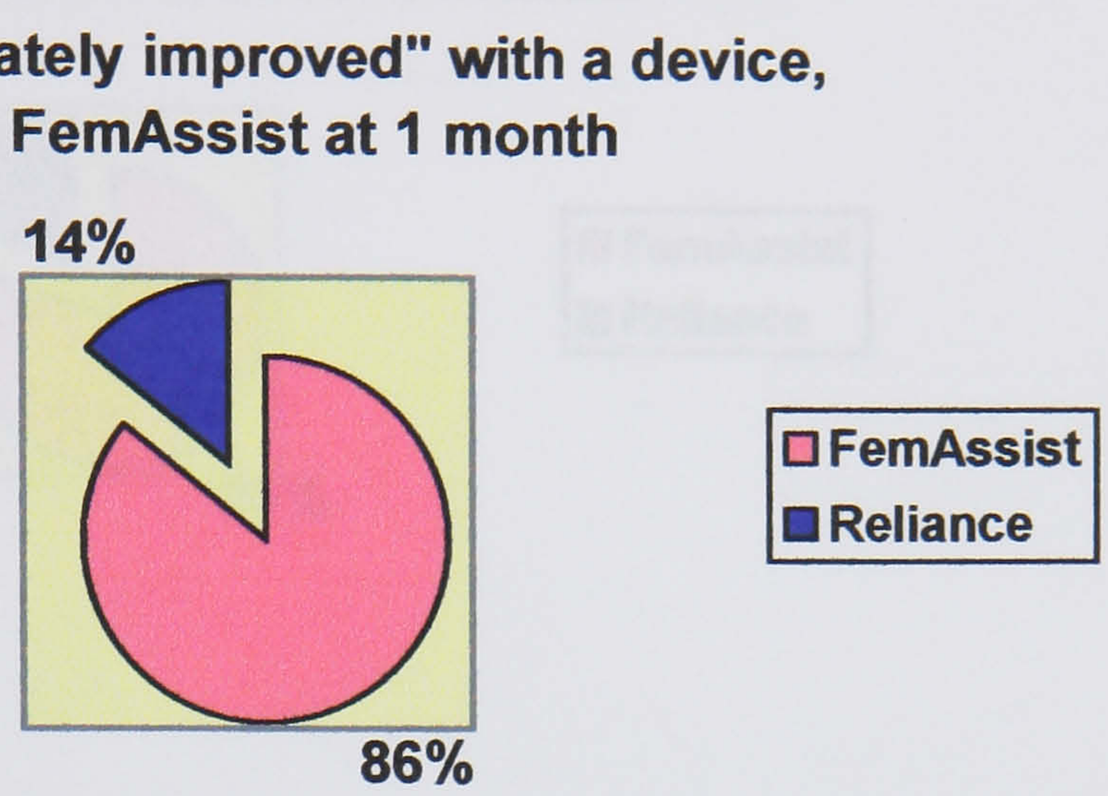


Figure 10.24 The proportion of women moderately improved with device use at 1 month (PWT).

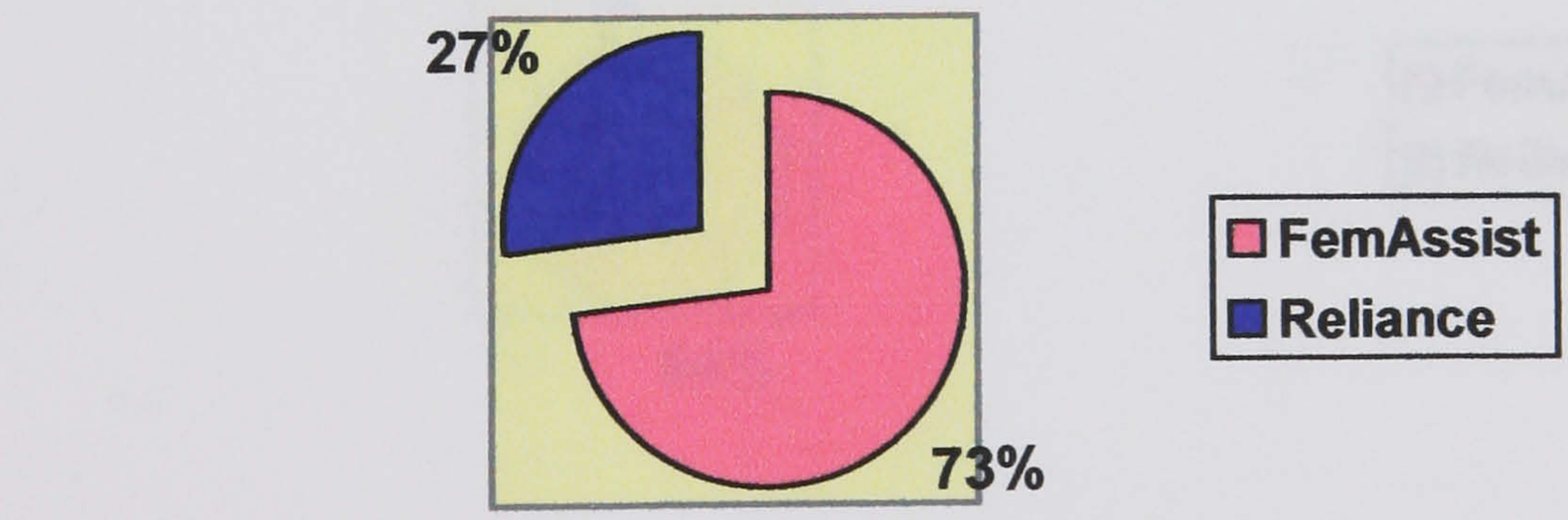


Figure 10.25 The proportion of women moderately improved with device use at 3 months (PWT).

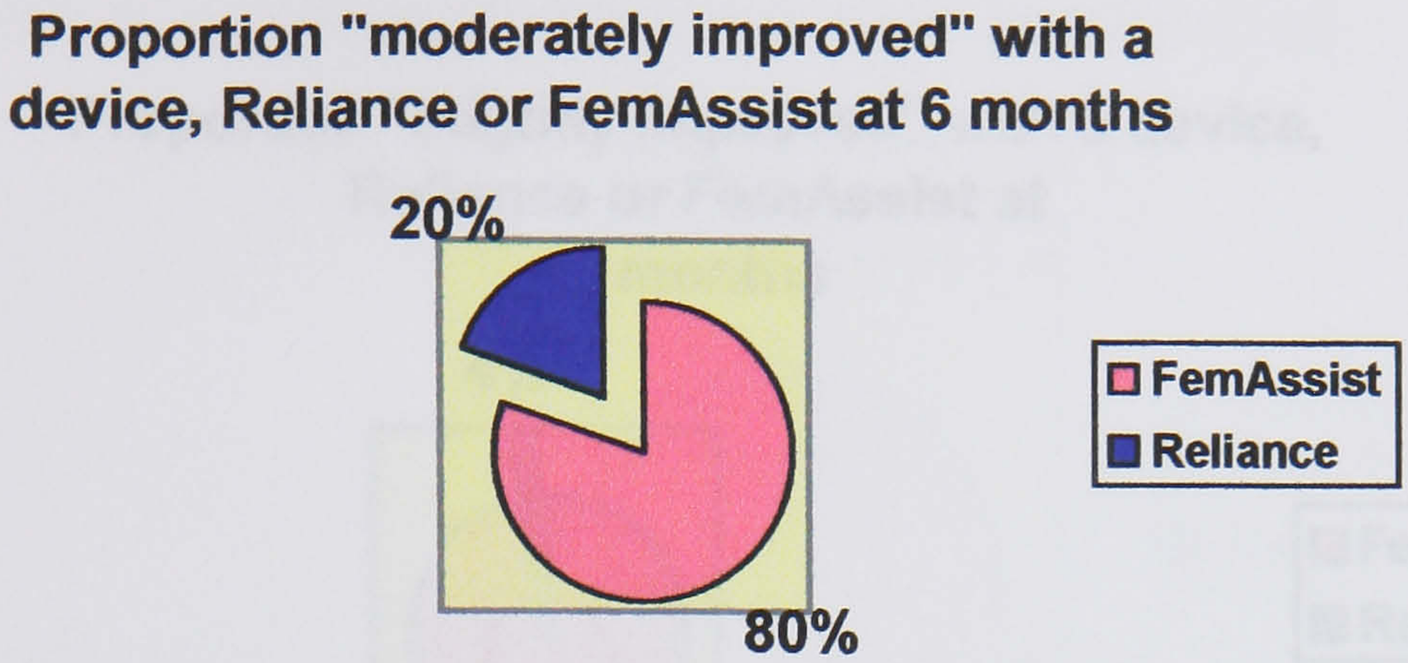


Figure 10.26 The proportion of women moderately improved with device use at 6 months (PWT).

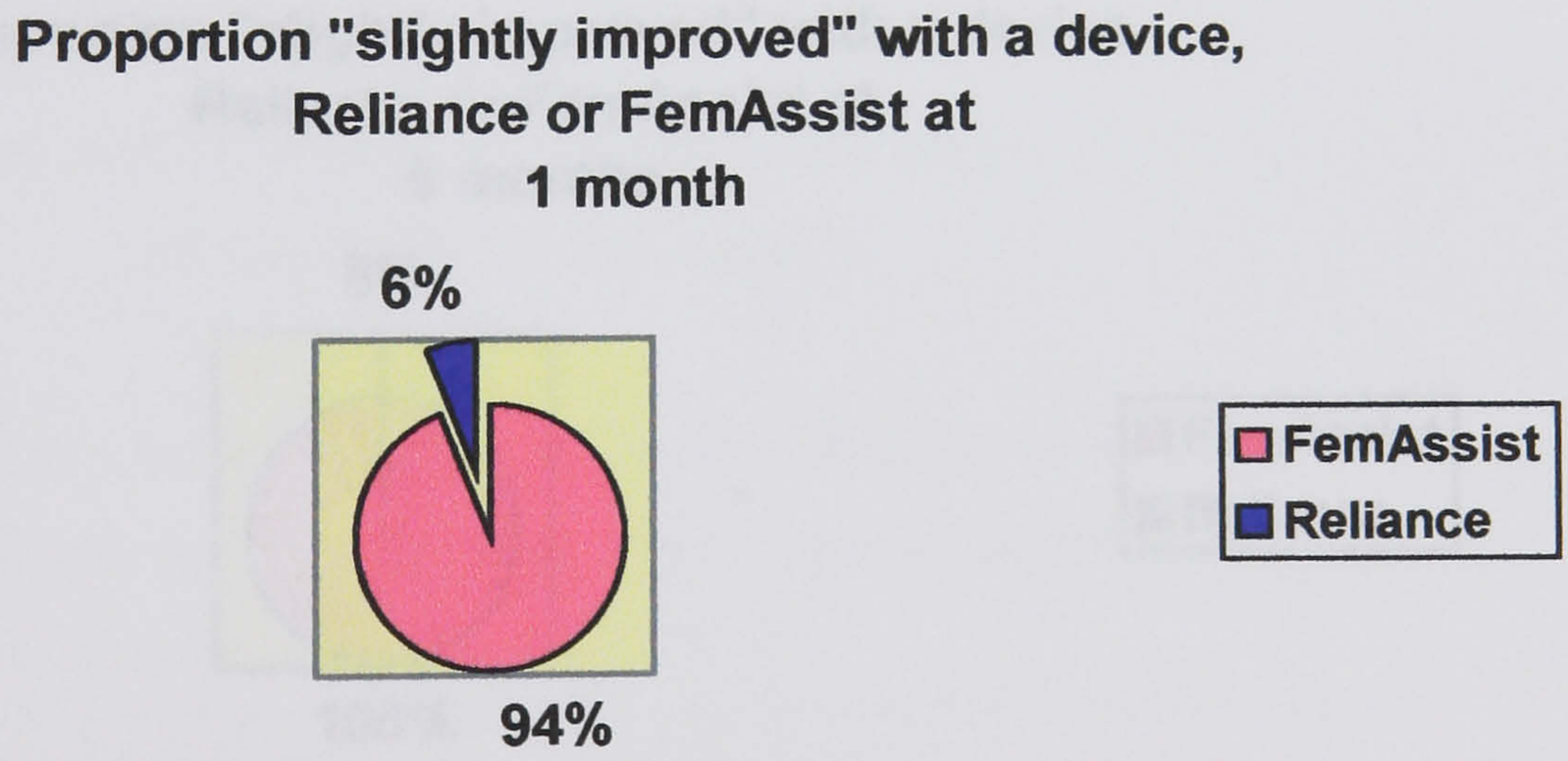


Figure 10.27 The proportion of women slightly improved with device use at 1 month (PWT).

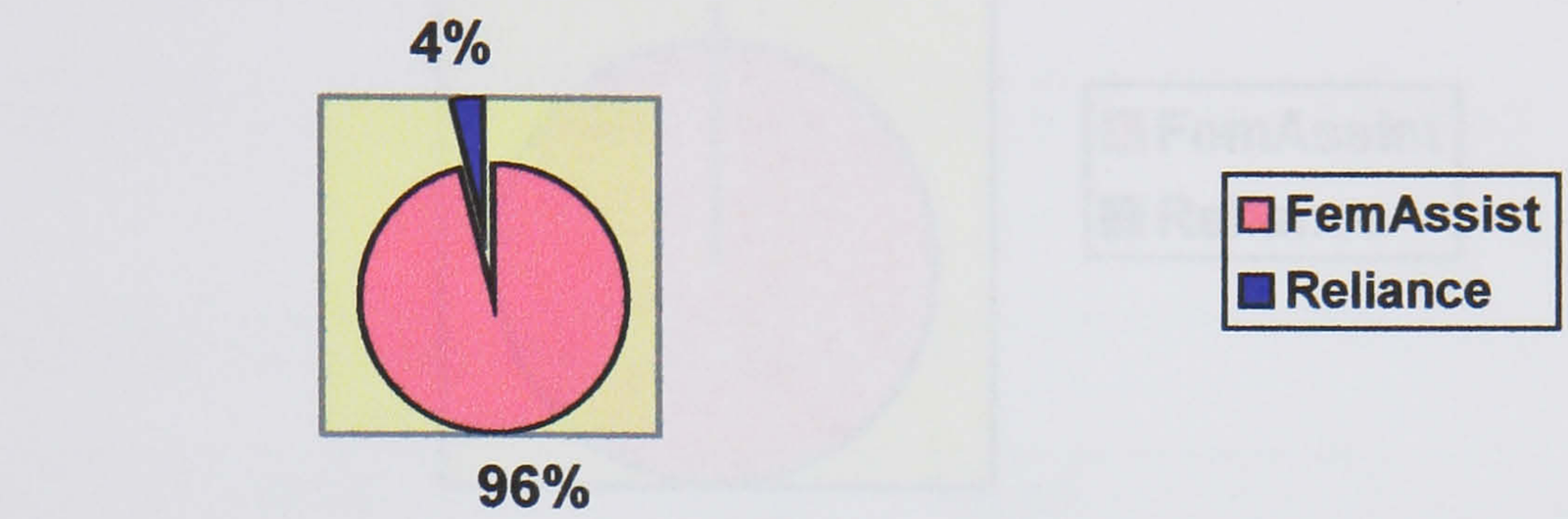


Figure 10.28 The proportion of women slightly improved with device use at 3 months (PWT).

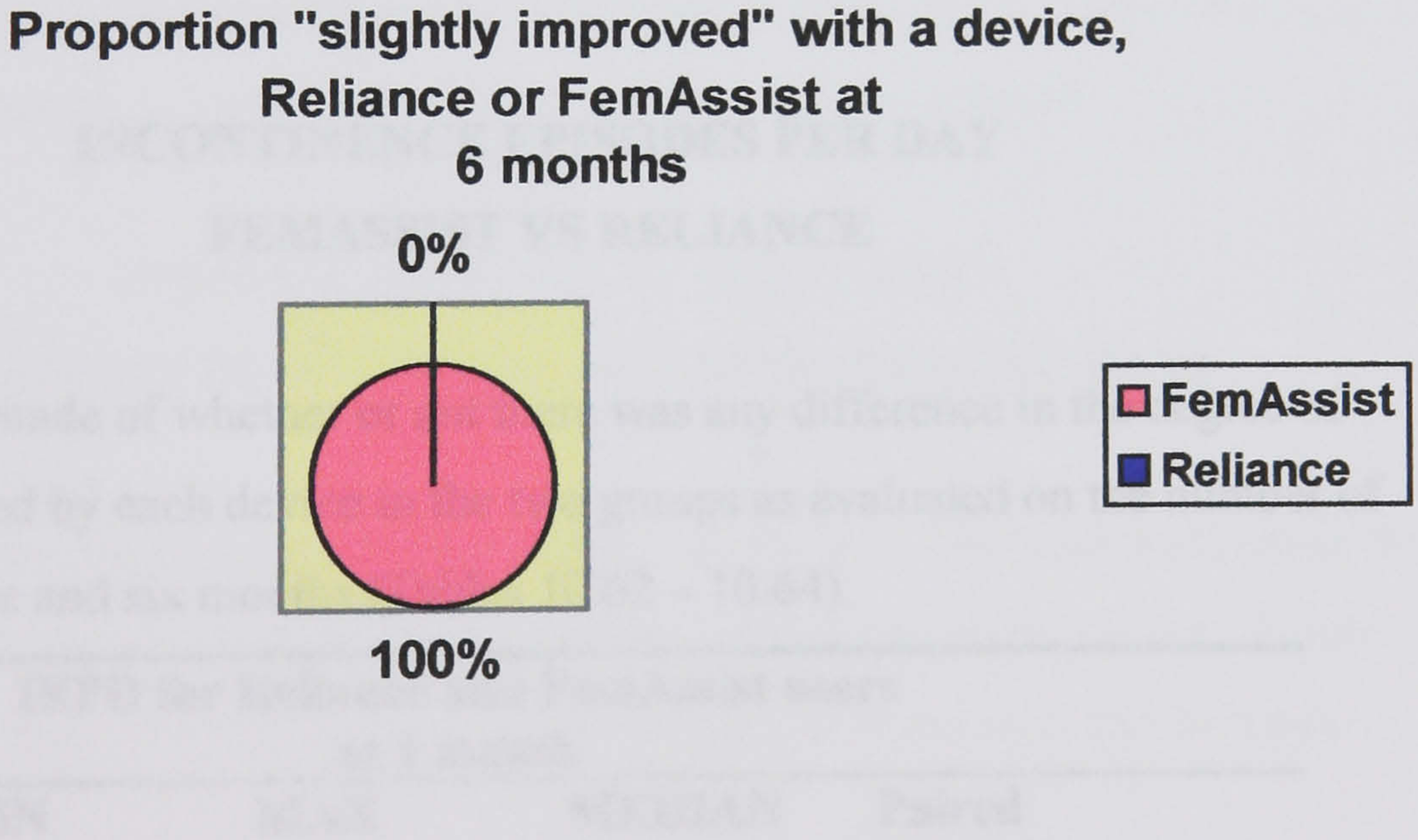


Figure 10.29 The proportion of women slightly improved with device use at 6 months (PWT).

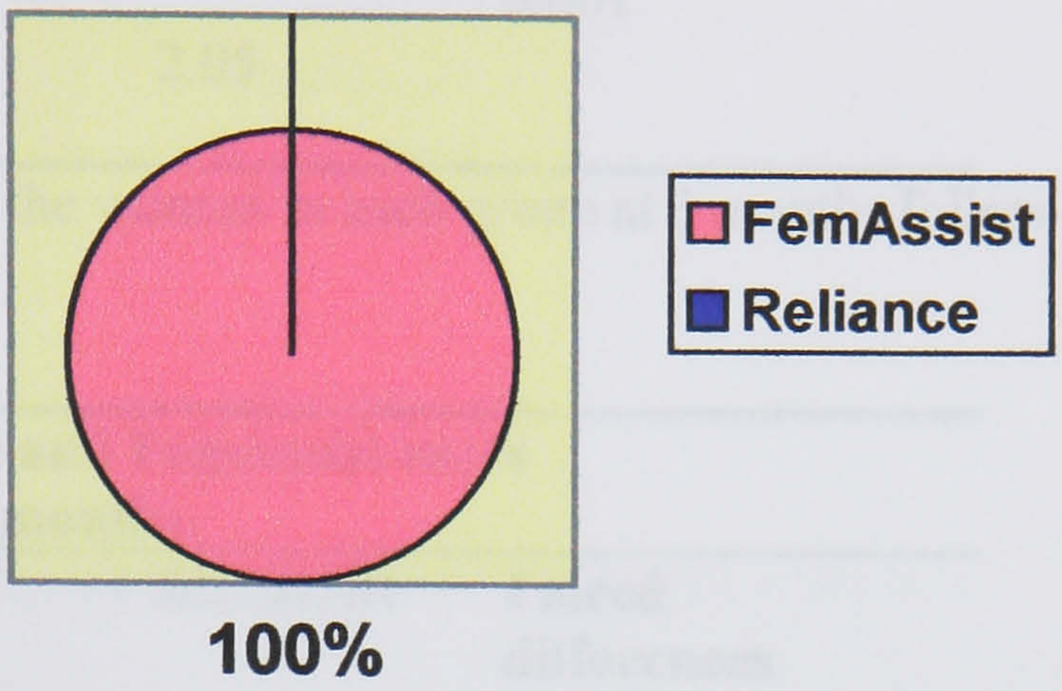


Figure 10.30 The proportion of women experiencing no change with device use at 1, 3 or 6 months (PWT).

It can be easily grasped that proportionally more women with GSI experienced a higher degree of control of urinary leakage using a Reliance device.

INCONTINENCE EPISODES PER DAY
FEMASSIST VS RELIANCE

Assessment was made of whether or not there was any difference in the degree of protection afforded by each device in the two groups as evaluated on the number of IEPD at one, three and six months (Tables 10.62 – 10.64).

IEPD for Reliance and FemAssist users at 1 month

	MIN	MAX	MEDIAN	Paired differences p-value
Reliance n=42	1	2	1.59	0.66
FemAssist n=47	1	2	1.63	

Table 10.62 The number of IEPD of the women in each group at 1-month follow-up assessment.

IEPD for Reliance and FemAssist users at 3 months				
	MIN	**MAX**	**MEDIAN**	**Paired differences p-value**
Reliance n=29	1	2	1.31	0.001
FemAssist n=41	1	3	2.05	

Table 10.63 The number of IEPD of the women in each group at 3 months follow-up assessment.

IEPD for Reliance and FemAssist users at 6 months				
	MIN	**MAX**	**MEDIAN**	**Paired differences p-value**
Reliance n=31	1	2	1.32	0.03
FemAssist n=36	0	2	1.00	

Table 10.64 The number of IEPD of the women in each group at 6 months follow-up assessment.

There was no significant difference between the groups at 1 month but significant differences were observed subsequently, with women using the Reliance having less incontinence episodes at 3 months and FemAssist better at 6 months.

INDIVIDUAL PATIENT RESPONSES (CHANGES IN INCONTINENCE EPISODES PER DAY)

The following data illustrates the proportion of women with GSI who were made dry or improved with use of a device based on the individual patient responses obtained from the urinary diary (IEPD) after 1,3, and 6 months of FemAssist and Reliance device use.

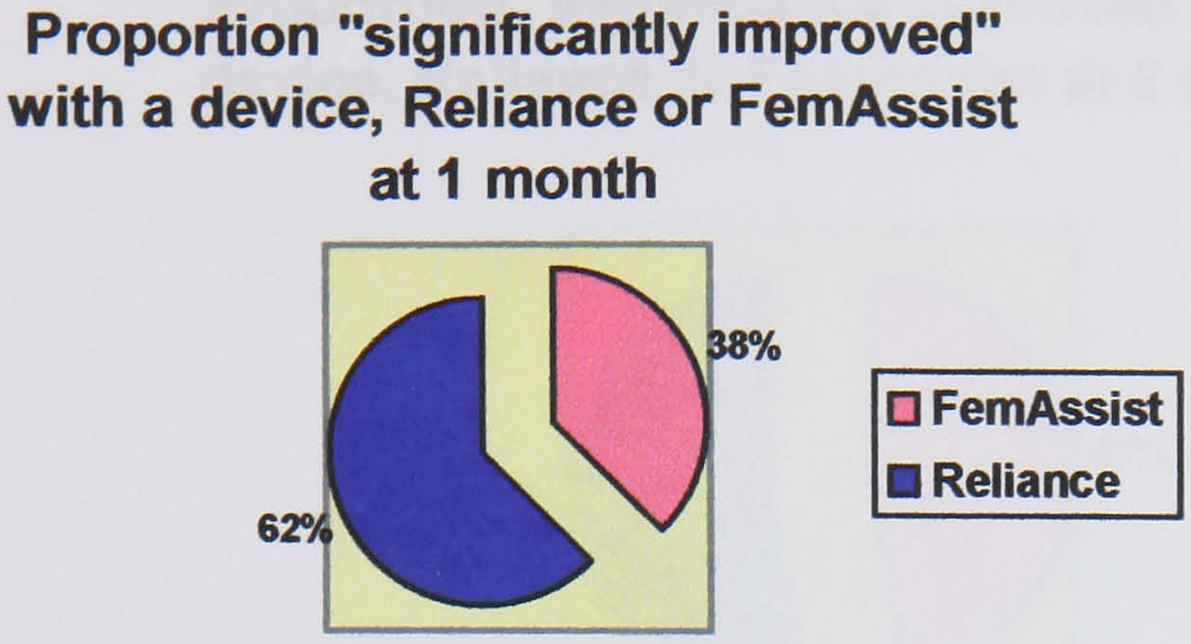


Figure 10.31 Proportion of women significantly improved with device use at 1 month (IEPD)

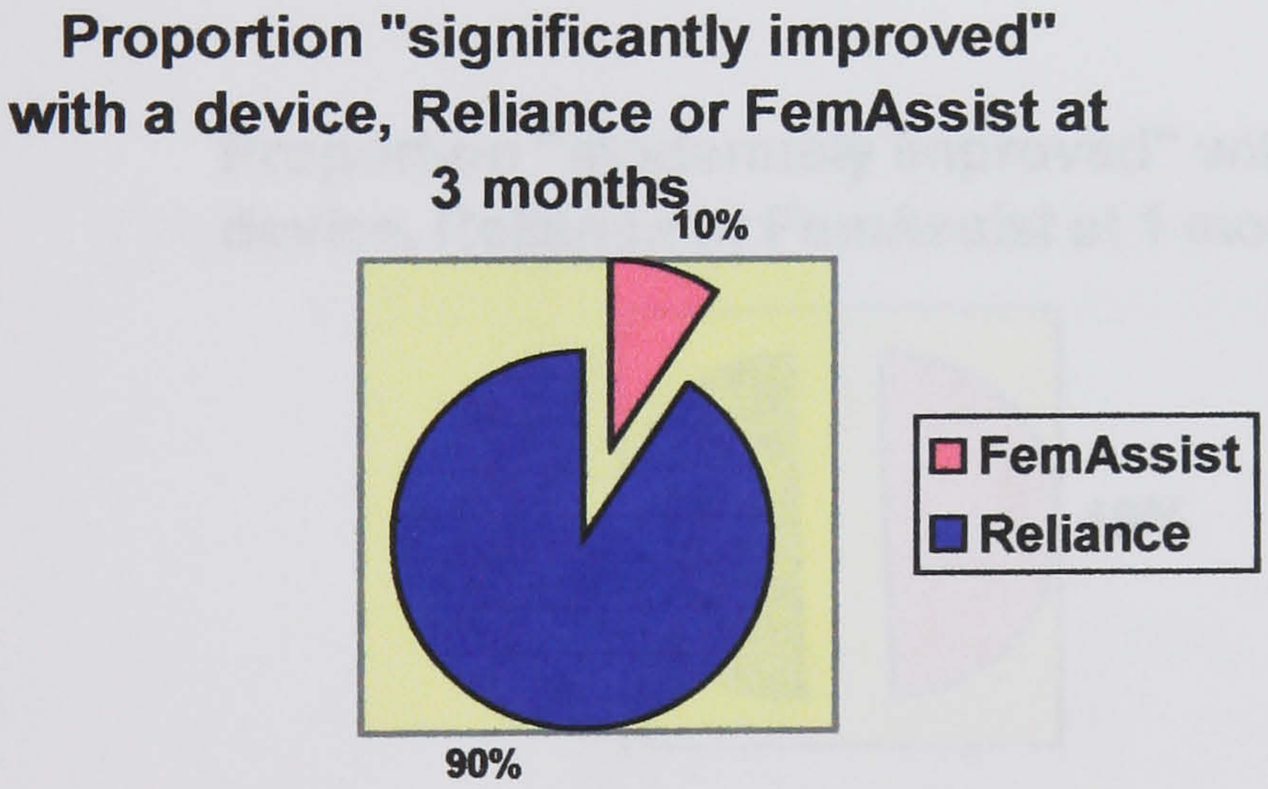


Figure 10.32 Proportion of women significantly improved with device use at 3 months (IEPD)

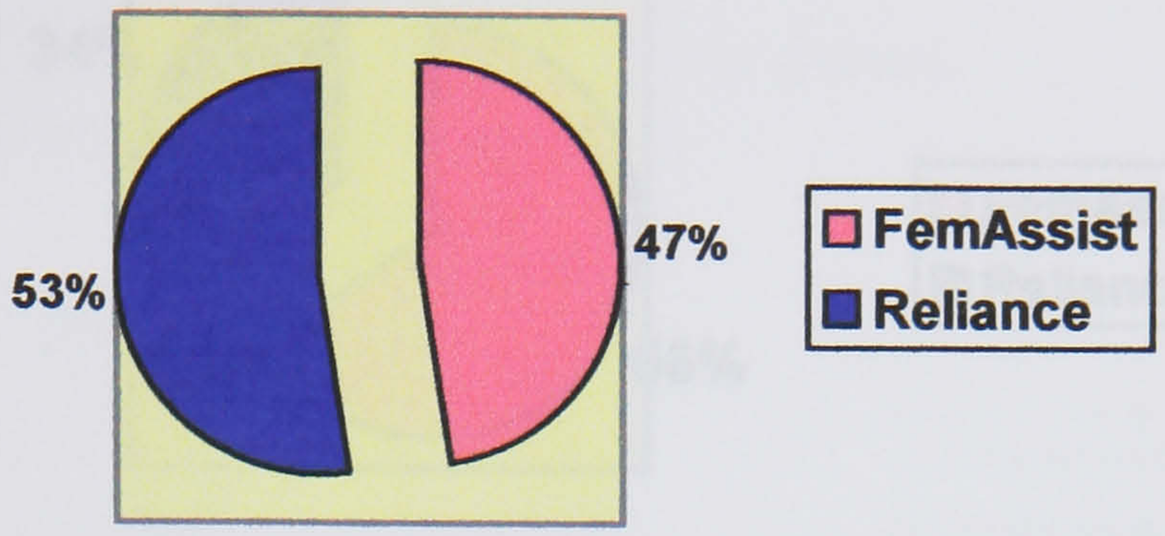


Figure 10.33 Proportion of women significantly improved with device use at 6 months (IEPD)

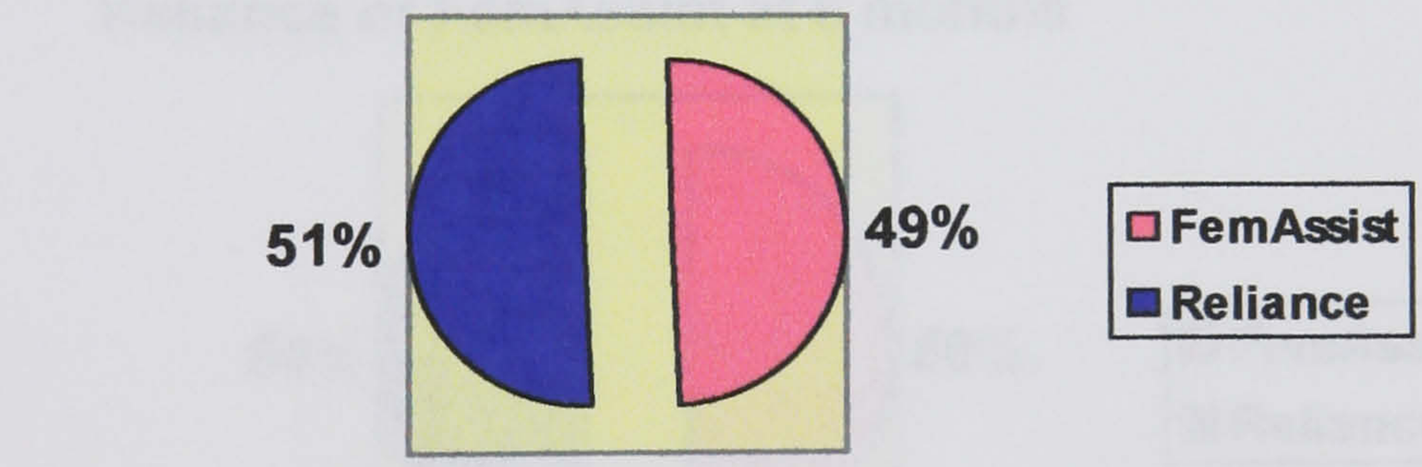


Figure 10.34 Proportion of women moderately improved with device use at 1 month (IEPD).

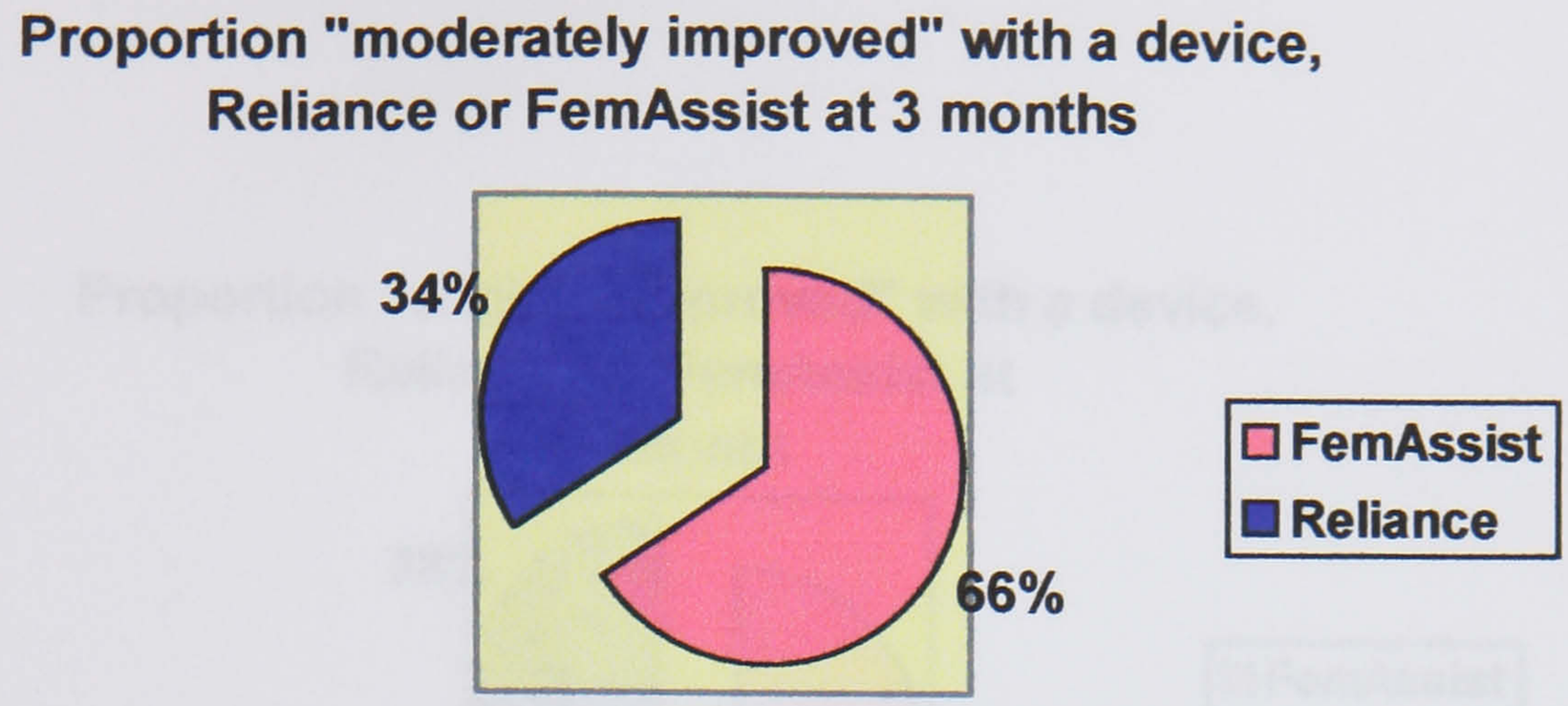


Figure 10.35 Proportion of women moderately improved with device use at 3 months (IEPD)

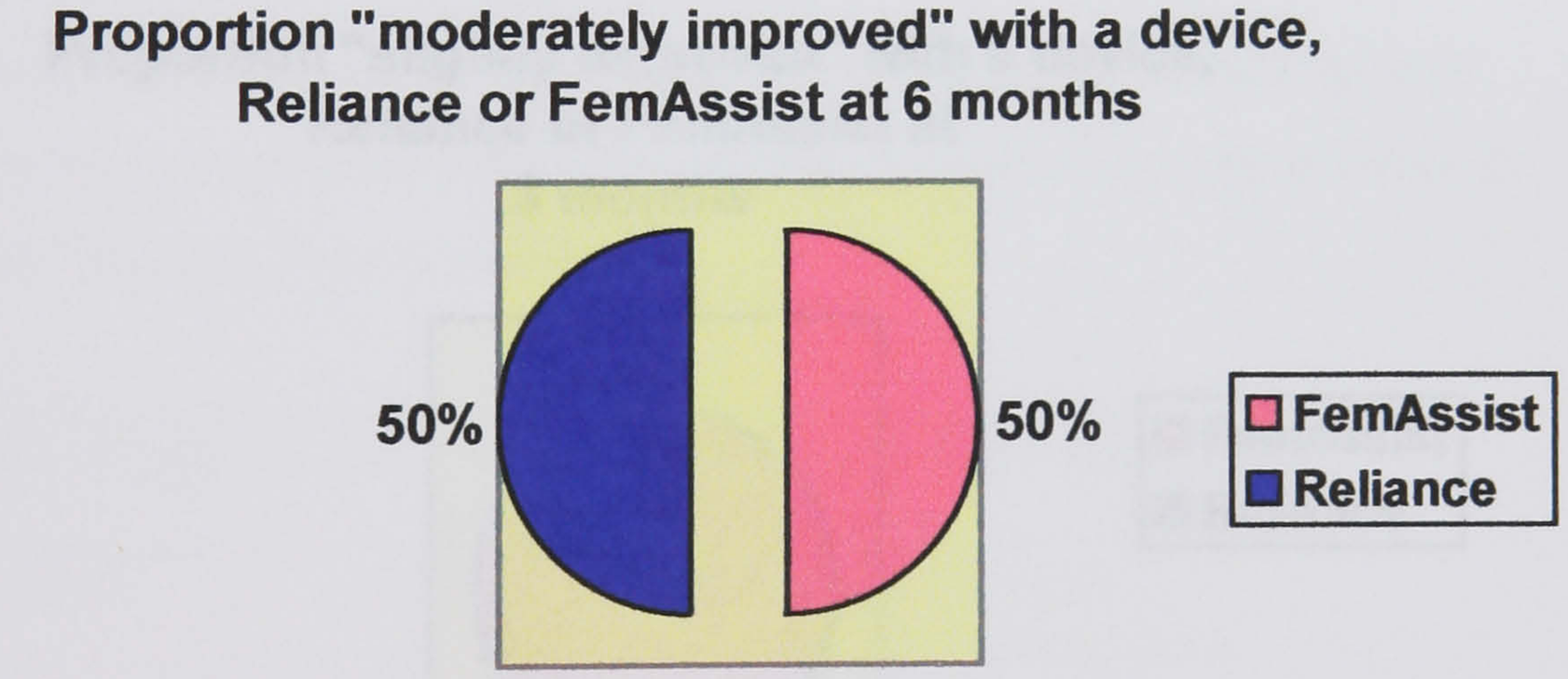


Figure 10.36 Proportion of women moderately improved with device use at 6 months (IEPD)

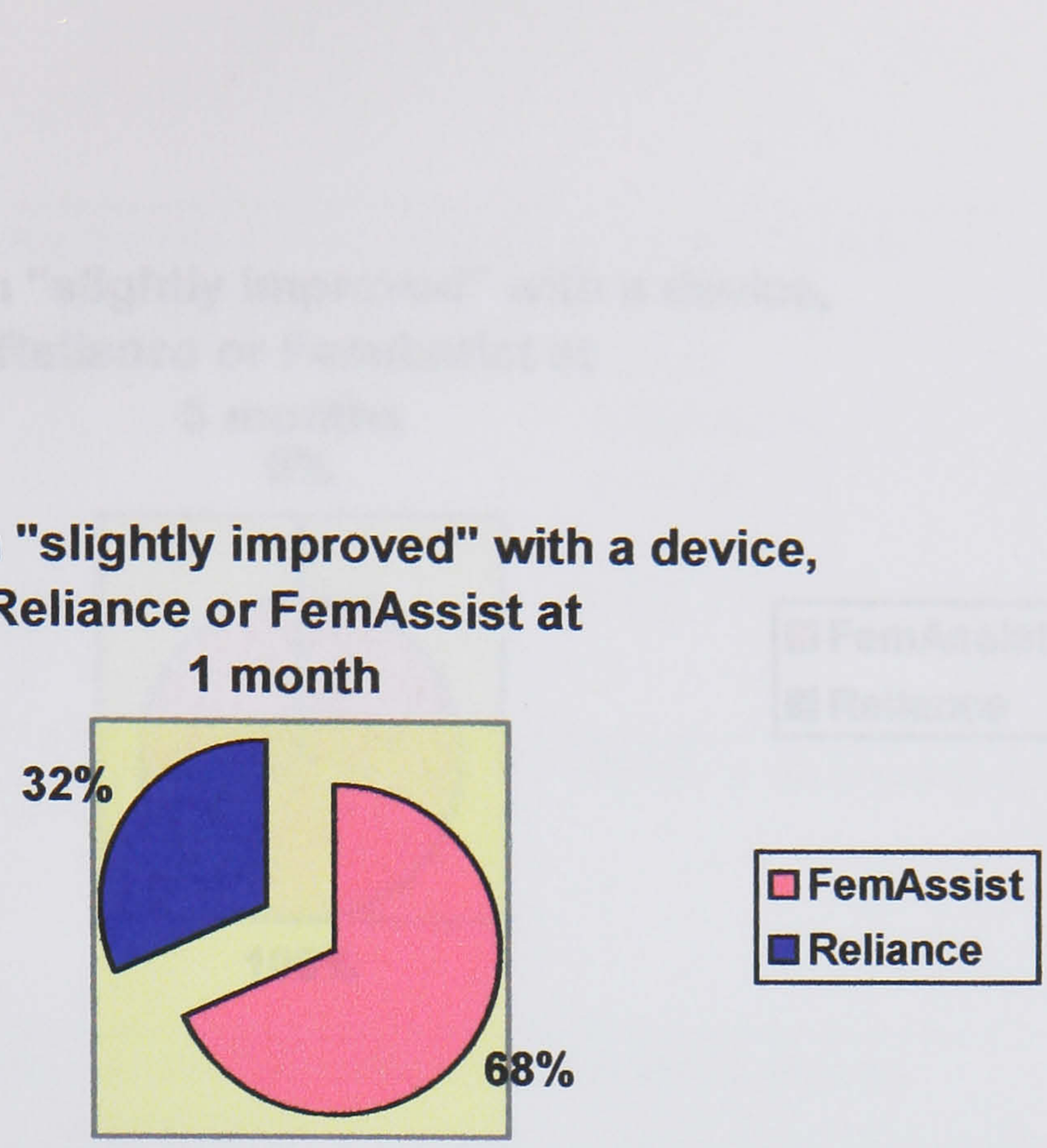


Figure 10.37 Proportion of women slightly improved with device use at 1 month (IEPD)

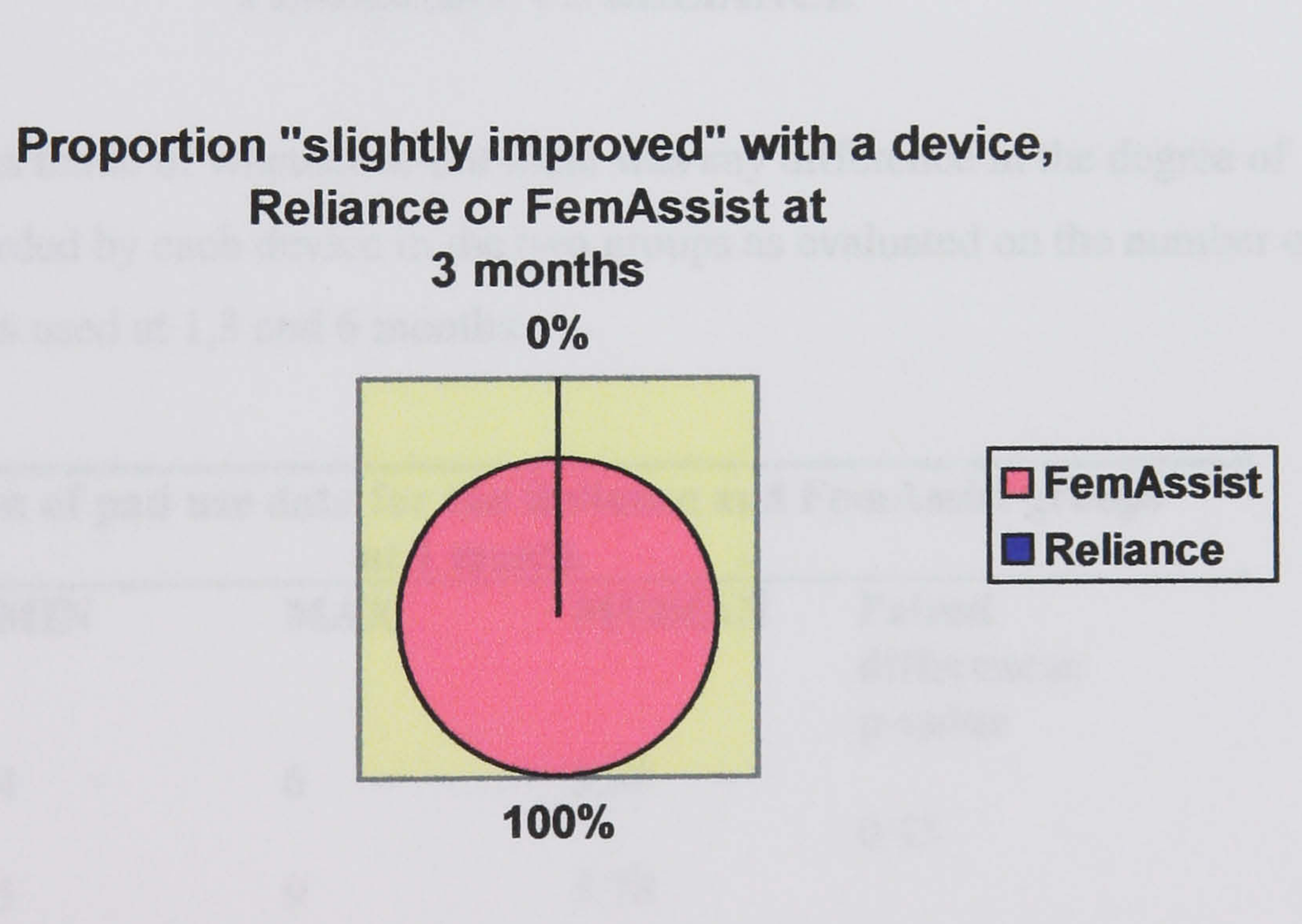


Figure 10.38 Proportion of women slightly improved with device use at 3 months (IEPD)

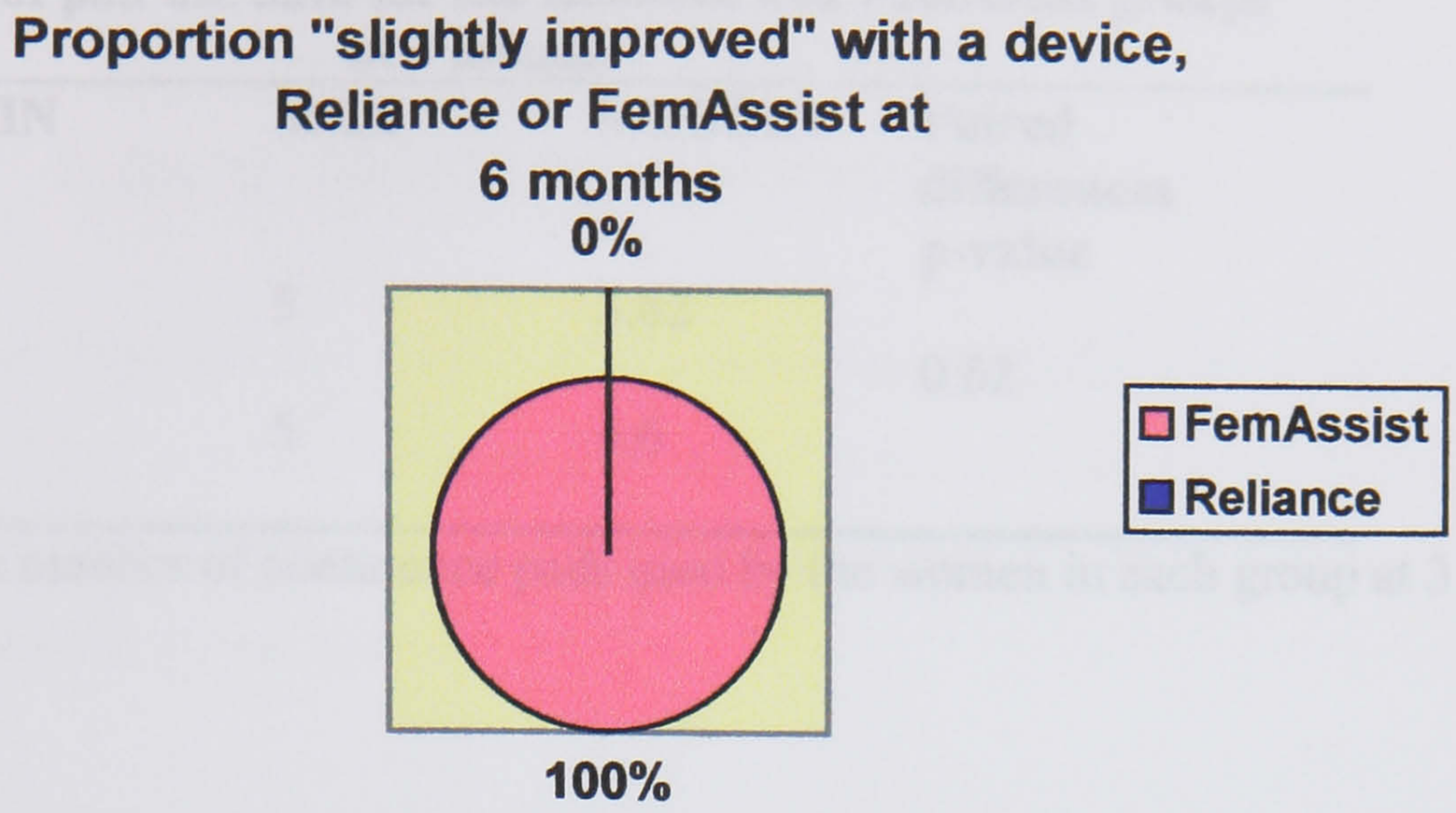


Figure 10.39 Proportion of women slightly improved with device use at 6 months (IEPD)

CONTINENCE PADS USED OVER FIVE DAYS
FEMASSIST VS RELIANCE

Assessment was made of whether or not there was any difference in the degree of protection afforded by each device in the two groups as evaluated on the number of continence pads used at 1,3 and 6 months.

Comparison of pad use data for the Reliance and FemAssist groups at 1 month

	MIN	MAX	MEDIAN	Paired differences p-value
Reliance n=42	4	6	5.00	0.43
FemAssist n=47	5	9	5.78	

Table 10.65 The number of continence pads used by the women in each group at 1 month.

Comparison of pad use data for the Reliance and FemAssist groups at 3 months				
	MIN	**MAX**	**MEDIAN**	**Paired differences p-value**
Reliance n=29	3	5	3.62	0.62
FemAssist n=41	4	5	4.6	

Table 10.66 The number of continence pads used by the women in each group at 3 months.

Comparison of pad use data for the Reliance and FemAssist groups at 6 months				
	MIN	**MAX**	**MEDIAN**	**Paired differences p-value**
Reliance n=31	3	5	3.45	0.55
FemAssist n=36	4	5	4.35	

Table 10.67 The number of continence pads used by the women in each group at 6 months.

There were no significant differences in the reduction in pad usage between the groups.

INDIVIDUAL PATIENT RESPONSES
(CHANGES IN CONTINENCE PAD USE)

The following data illustrates the proportion of women with GSI who were made dry or improved with use of a device based on the individual patient responses obtained from the urinary diary (continence pads used over 5 days) after 1,3, and 6 months of FemAssist and Reliance device use.

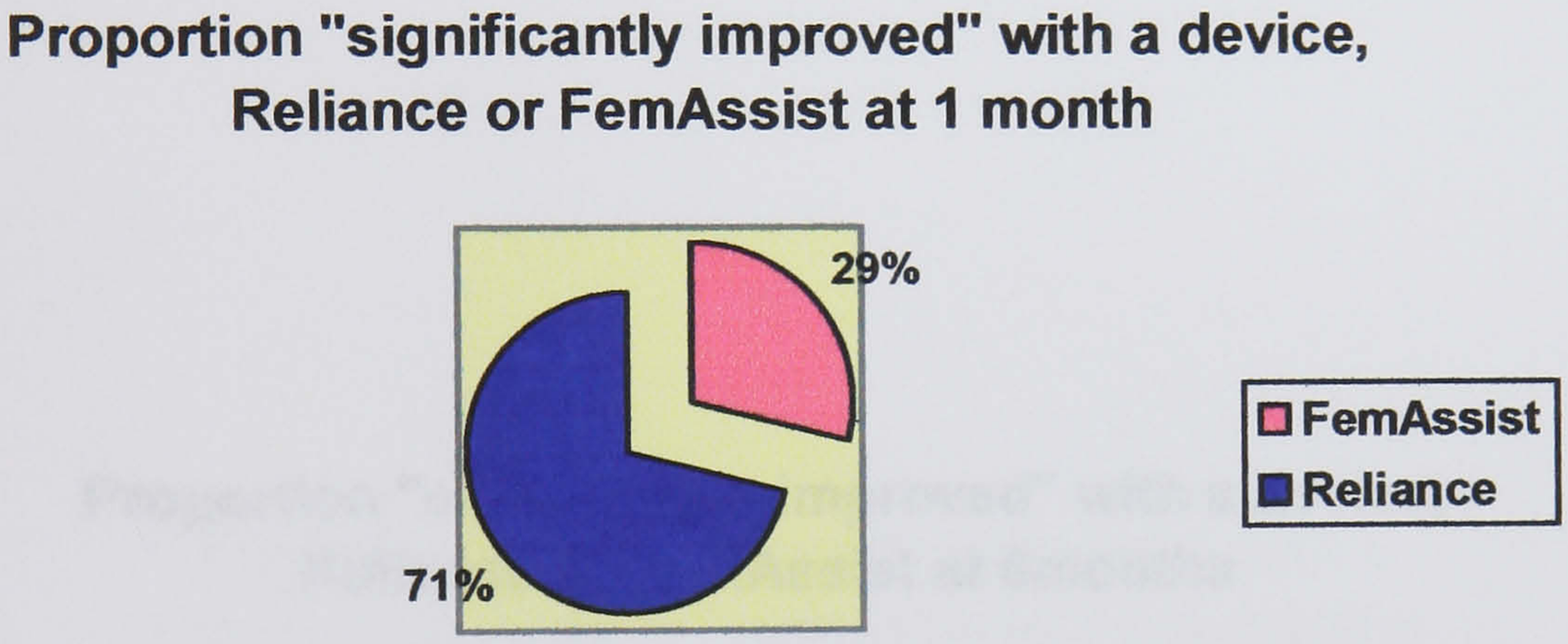


Figure 10.40 Proportion of women significantly improved with a device at 1 month (pads used).

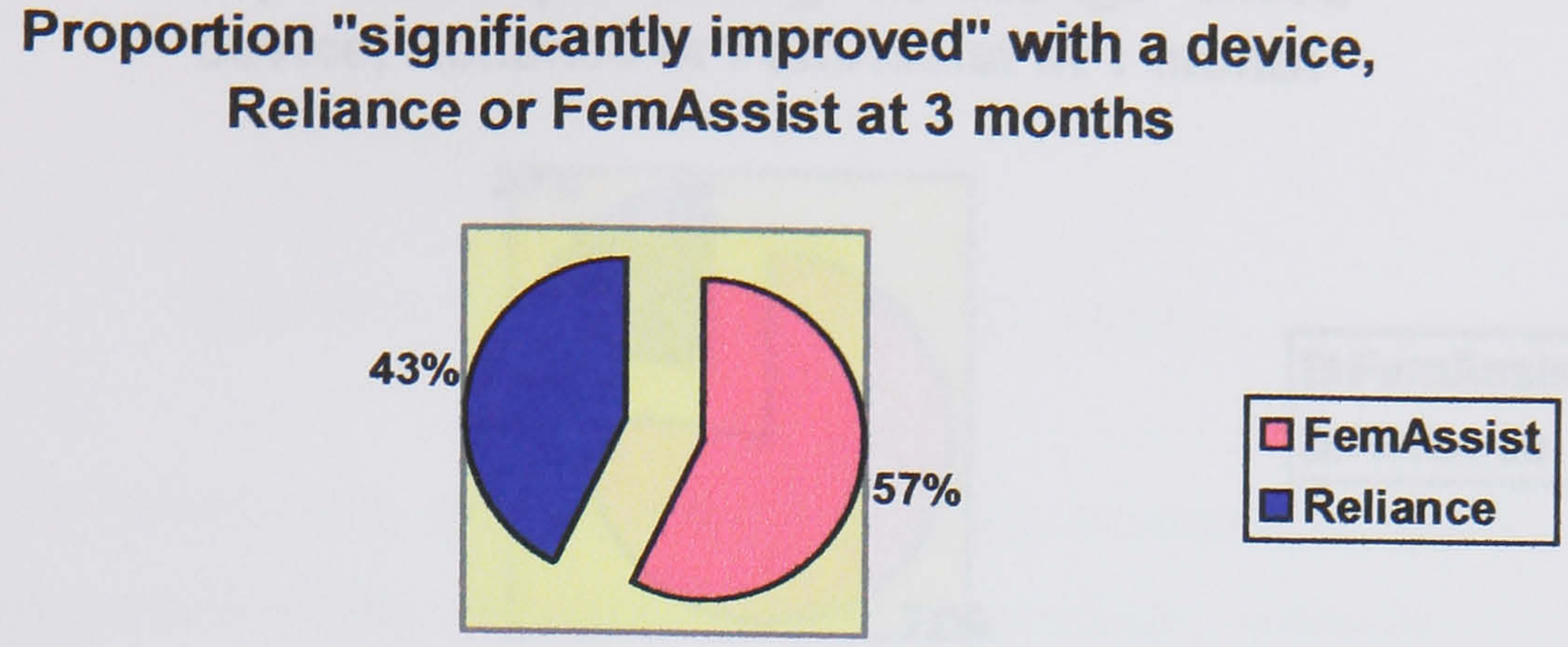


Figure 10.41 Proportion of women significantly improved with a device at 3 months (pads used).

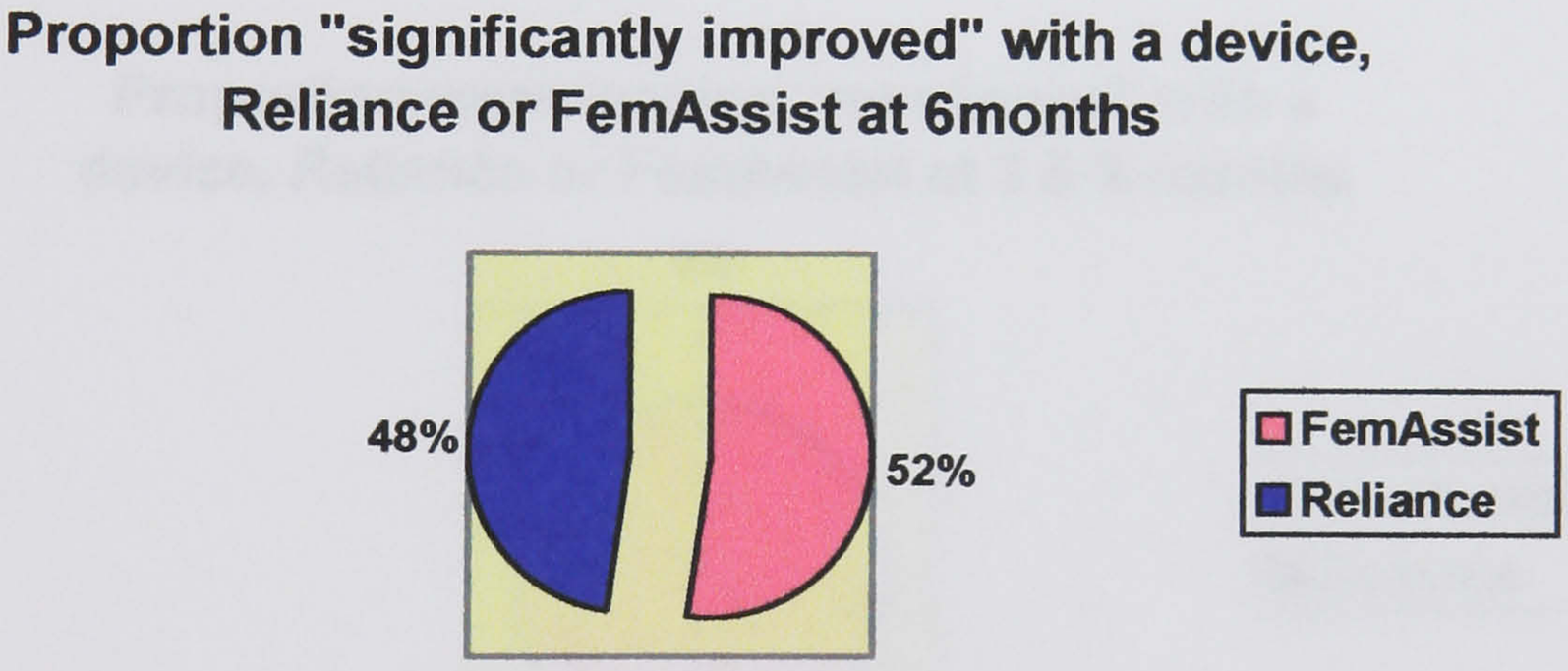


Figure 10.42 Proportion of women significantly improved with a device at 6 months (pads used).

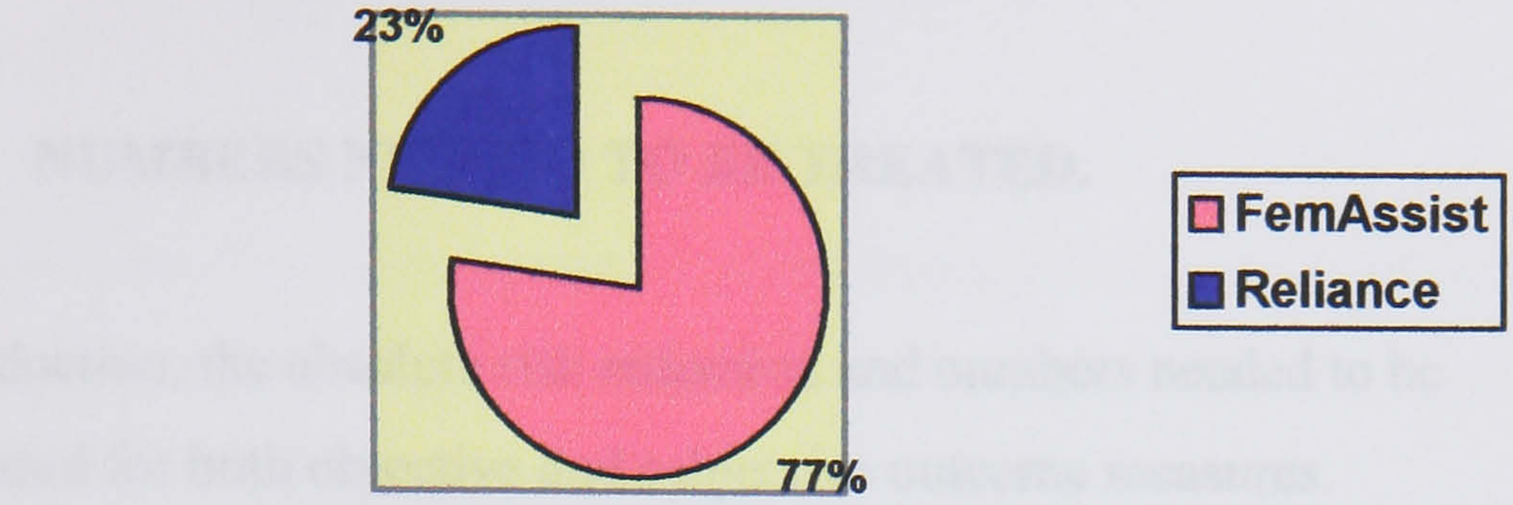


Figure 10.43 Proportion of women experiencing no change with a device at 1 month (pads used).

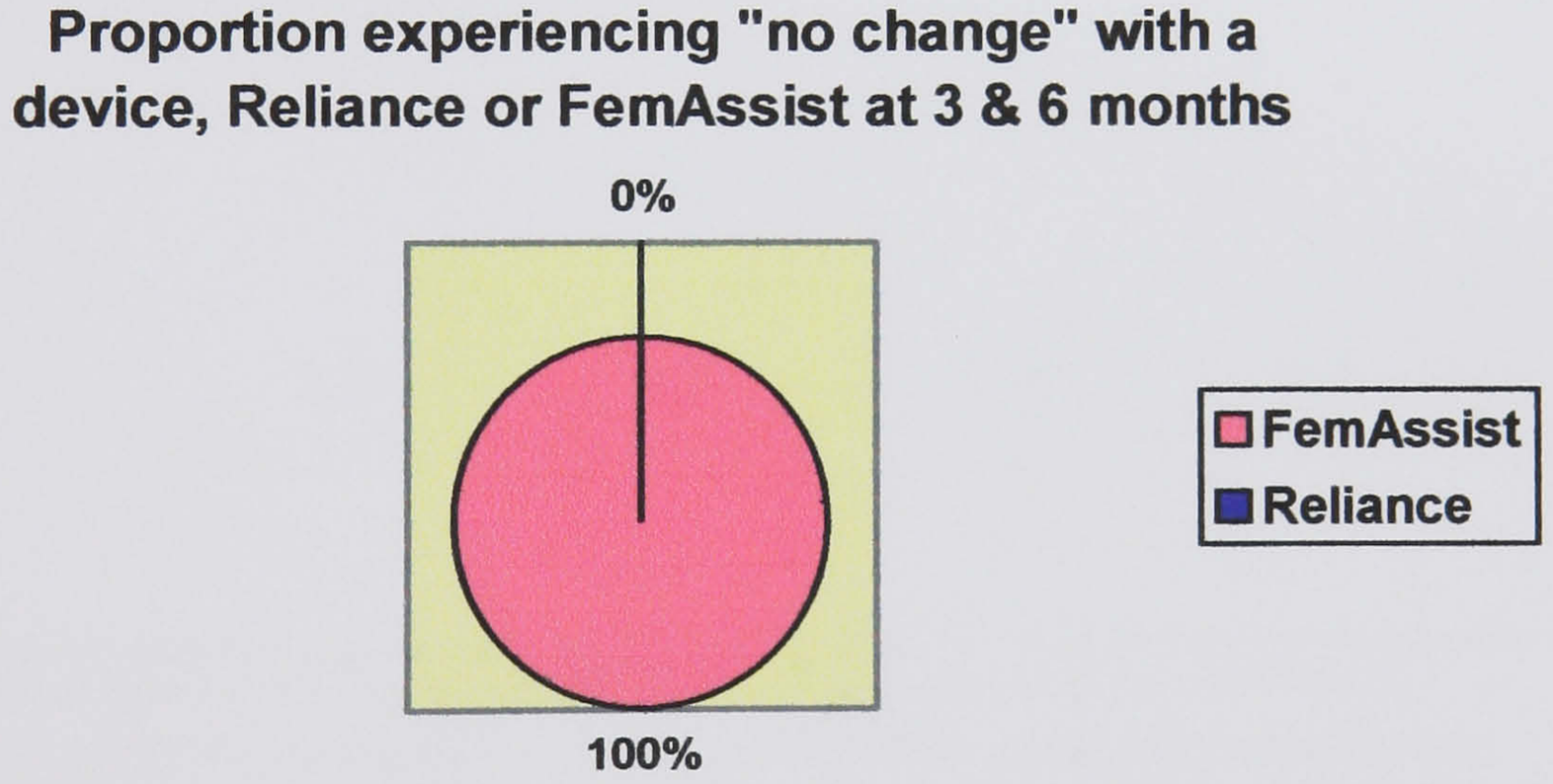


Figure 10.44 Proportion of women experiencing no change with a device at 3 and 6 months (pads used).

RELATIVE RISK REDUCTION

ABSOLUTE RISK REDUCTION

NUMBERS NEEDED TO BE TREATED.

The relative risk reduction, the absolute risk reduction and numbers needed to be treated were calculated for both objective and subjective outcome measures. Relative risk reduction is the reduction of adverse events achieved by a treatment, expressed as a proportion of the control rate. It is the difference in event rates between the control and treatment groups, divided by the event rate in the control group. The absolute risk reduction or attributable risk reduction is the difference in event rates between the control (pre-treatment) and treatment groups. The "number needed to be treated" is the number of patients who must be treated in order to prevent one adverse event.

INCONTINENCE EPISODES PER DAY ON URINARY DIARY
CONTINENCE PADS USED OVER 5 DAYS

RELIANCE GROUP

Calculations were made for the mean number of incontinence episodes and pads used per 5 days recorded in the urinary diary of the Reliance group before and at completion of the trial and are illustrated in table 10.68

Reliance group rates of adverse events:
IEPD and pads used per 5 days

	Rates of adverse events				
	Before Treatment	**Treat with Reliance Device**	**Relative Risk reduction**	**Absolute risk reduction**	**Number needed to be treated**
2 or more incontinence episodes/day	1	0.12	88%	0.88	1.1
3 or more pads used per 5 days	1	0.31	69%	0.69	1.4

Table 10.68 Incontinence episodes per day (IEPD) and pads used per five days illustrated as rates of adverse events before treatment (control) and after device use (treatment). Included are the relative risk reduction, the absolute risk reduction and numbers needed to be treated.

FEMASSIST GROUP

A table of similar adverse events is shown for the FemAssist group before and after device use, with the calculation of the relative risk reduction, the absolute risk reduction and numbers needed to be treated as described previously (Table 10.69).

FemAssist group rates of adverse events:

IEPD and pads used per 5 days

Rates of adverse events					
Before Treatment	**Treat with FemAssist Device**	**Relative Risk reduction**	**Absolute risk reduction**	**Number needed to be treated**
2 or more incontinence episodes/day	1	0.06	94%	0.94	1.1
3 or more pads used per 5 days	1	0.36	64%	0.64	1.6

Table 10.69. Incontinence episodes and pads used per five days illustrated as rates of adverse events before treatment (control) and after device use (treatment). Included are the relative risk reduction, the absolute risk reduction and numbers needed to be treated.

PAD WEIGHT TEST

RELIANCE GROUP

The table illustrates the mean pad weight test gains for the Reliance group before and after 6 months of device use, with the calculation of the relative risk reduction, the absolute risk reduction and numbers needed to be treated (Table 10.70).

Reliance group rates of adverse events
(mean PWT gains)

Rates of adverse events					
Mean PWT Gains	**Treat with Reliance Device**	**Before Treatment**	**Relative Risk reduction**	**Absolute risk reduction**	**Number needed to be treated**
3g or less	0.625	0.146	76.6%	0.479	2.1

Table 10.70 The mean PWT gain for the Reliance group before and after treatment for women with three grams or less loss on testing as an adverse event. Included are the relative risk reduction, the absolute risk reduction and numbers needed to be treated.

FEMASSIST GROUP

Table 10.71 similarly illustrates the mean pad weight test gains data obtained for the FemAssist group.

FemAssist group rates of adverse events (Mean PWT Gains)

	Rates of adverse events				
Mean PWT Gains	**Treat with FemAssist Device**	**Before Treatment**	**Relative Risk reduction**	**Absolute risk reduction**	**Number needed to be treated**
3g or less	0.302	0.038	87.4%	0.264	3.8

Table 10.71 The mean PWT gain for the FemAssist group before and after treatment for women with two grams or more and one gram or less loss on testing as an adverse event. Included are the relative risk reduction, the absolute risk reduction and numbers needed to be treated.

CHAPTER ELEVEN

QUALITY OF LIFE AND IMPACT OF SYMPTOMS AT BASELINE AND AS A CONSEQUENCE OF DEVICE USE

The results will be presented under the following headings for each device group and each QoL questionnaire:

1. Baseline quality of life scores

2. Quality of life scores after treatment

3. Comparison of pre and post treatment scores

4. Aggregated baseline data (FemAssist and Reliance patients pre-treatment) compared with population norms (UK SF-36)

5. Comparison of post treatment scores with population norms (UK SF-36)

The following inter-group (FemAssist Vs Reliance) comparisons will be presented:

- Groups comparable at baseline
- Comparison of post treatment QoL scores

There were 48 copies of the Kings Health and SF-36 questionnaires returned by patients randomised to the Reliance group and 53 by the women randomised to the FemAssist group. All were completed correctly and all questions answered. Each sub scale of the Kings Health Questionnaire has a maximum score of 100 and minimum of 0, a maximum score indicating the worst possible impairment in that domain and a minimum score no impairment at all.

Each sub scale of the UK SF-36 questionnaire similarly has a maximum score of 100 and minimum of 0, but a maximum score indicates no impairment at all in that domain and a minimum score the worst possible impairment.

The number of women completing 6 months follow-up is shown in Table 11.1. In Total 69 (68.9%) women completed follow-up QoL questioning. All the questionnaires were completed correctly. The percentage follow-up for each device is

shown in Figure 11.1. A greater percentage of women completing the questionnaires and the study had used the FemAssist device.

Stage	Reliance	FemAssist	Total
Enrolment	48	53	101
Completed follow-up (%)	31 (64.6%)	36 (67.9%)	67 66.3(%)
Missing data	17 (35.4%)	17 (32.1%)	34 (33.7%)

Table 11.1 The number of women completing the SF-36 and KHQ quality of life questionnaires at enrolment into the study and at 6-month follow-up.

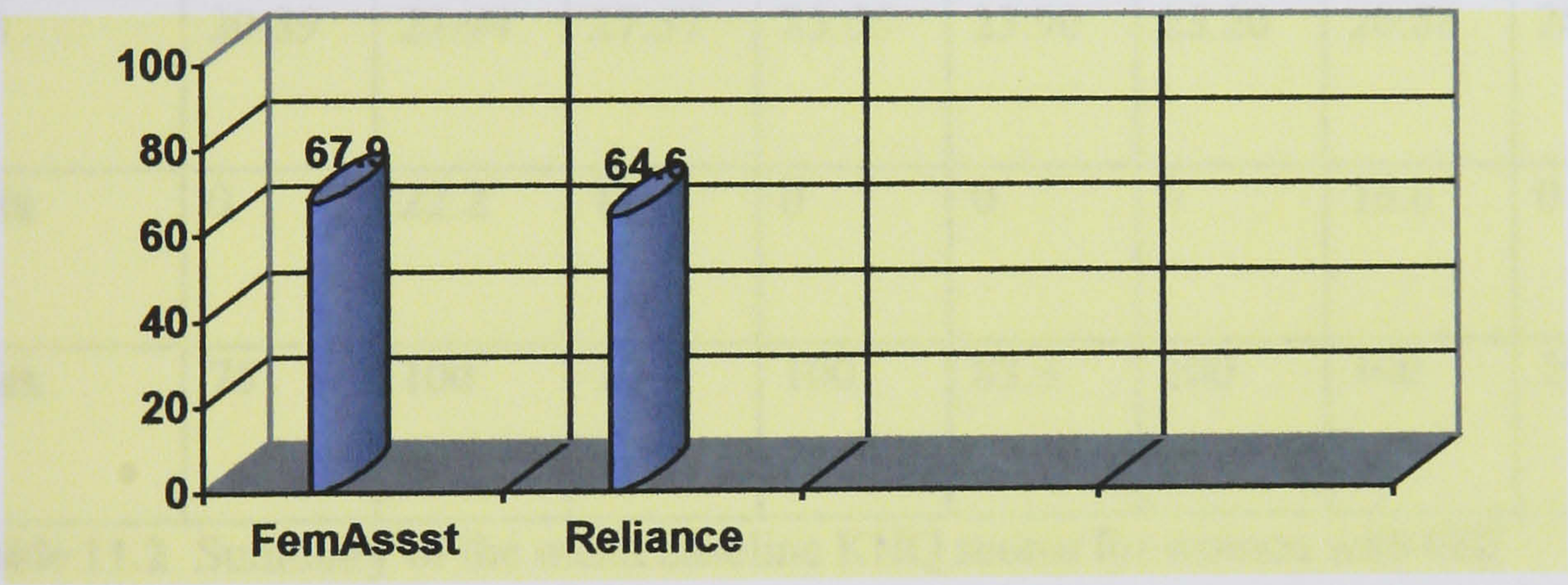


Figure 11.1 Women completing QoL questionnaires at follow-up, for each group. Reliance (n=31); FemAssist (n=36). Percentage values above bars.

1A BASELINE QUALITY OF LIFE SCORES

RELIANCE GROUP

KINGS HEALTH QUESTIONNAIRE

The baseline Kings Health Questionnaire quality of life scores for women randomised to use the Reliance device (n=48) are illustrated in table 11.2 and figure 11.2.

MEAN SCORES ON THE DOMAINS OF THE KINGS HEALTH QUESTIONNAIRE PRE TREATMENT									
Domains	**GHP**	**InImp**	**EL**	**RL**	**S/E**	**PersL**	**PhysL**	**SL**	**SM**
Mean	28.9	75.9	40.8	51	26.7	28.8	58.5	34.4	53.5
SD	20.89	23.94	27.57	25.66	23.90	23.20	20.88	26.06	19.15
Min	0	22.2	11	0	0	0	16.6	0	26.6
Max	75	100	100	100	83.3	100	100	100	80

Table 11.2 Summary of the mean baseline KHQ scores for women with GSI randomised to use the Reliance device. SD = standard deviation, Min = minimum value recorded, Max = maximum recorded. {GHP = General health perception, InImp = Incontinence impact, EL = Emotional limitation, RL = Role limitation, S/E = Sleep/ energy disturbance, PersL = Personal limitation, PhysL= Physical limitation, SL = Social limitation, SM = Severity measures.}

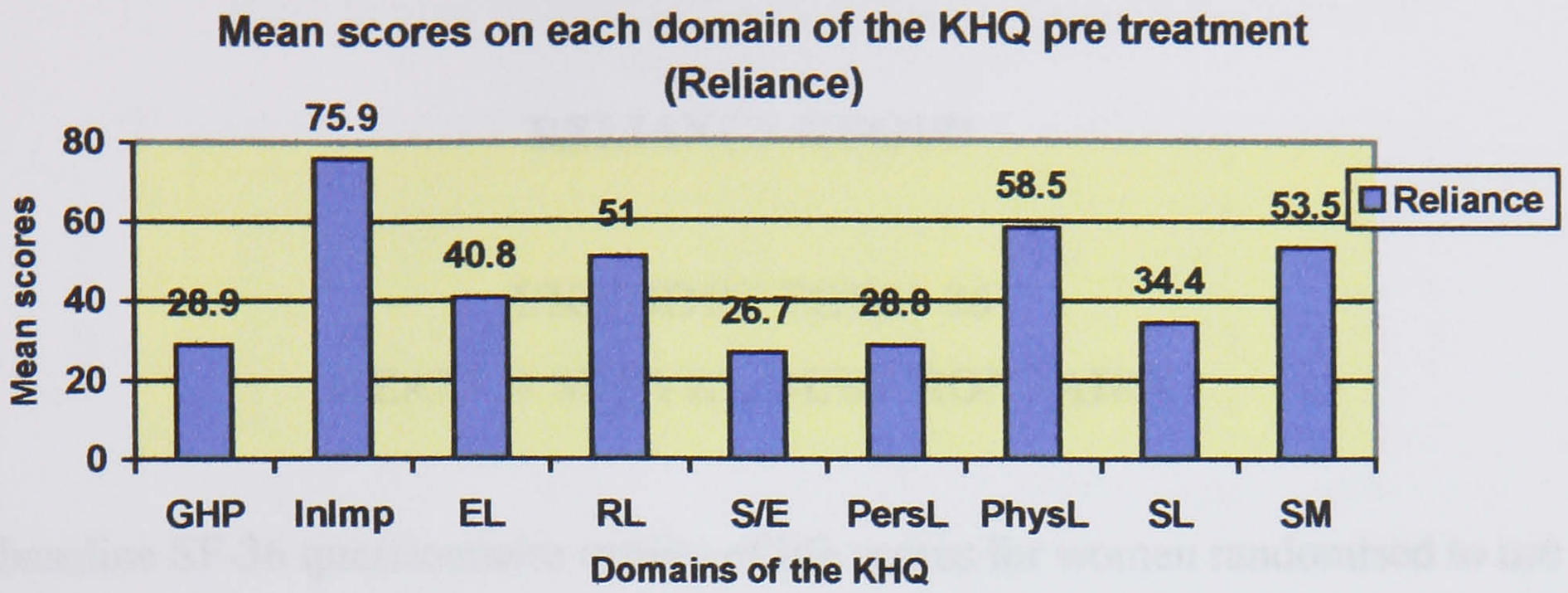


Figure 11.2 Mean baseline scores on each domain of the KHQ for women with GSI randomised to use the Reliance device.

The majority of women completing the KHQ considered their general health to be good. Incontinence impact scores were higher than those of all other domains. Sleep and energy were least affected and personal and social limitation was slightly affected while emotional limitation was moderately higher in comparison. Physical and role limitations were moderately influenced.

1B BASELINE QUALITY OF LIFE SCORES

RELIANCE GROUP

UK SHORT FORM-36
HEALTH SURVEY QUESTIONNAIRE

The baseline SF-36 questionnaire quality of life scores for women randomised to use the Reliance device (n=48) are illustrated in table 11.3 and figure 11.3.

MEAN SCORES ON THE DOMAINS OF THE UK SHORT FORM-36 PRE TREATMENT								
Domains	**PF**	**SF**	**PRL**	**ERL**	**MH**	**E/F**	**PAIN**	**GHP**
Mean	68.3	68.6	36.5	62.5	60.7	53.4	61.6	60.3
SD	5.10	5.66	8.03	5.04	3.66	5.52	5.13	3.13
Min	59	58	20	50	54	40	50	54
Max	80	78	50	71	66	65	74	69

Table 11.3 Summary of the mean baseline scores for women with GSI randomised to use the Reliance device. SD = standard deviation, Min = minimum value recorded, Max = maximum recorded. [PF = physical function, SF = social function, PRL = physical role limitation, ERL = emotional role limitation, MH = mental health, E/F = energy/fatigue, GHP = general health perception]

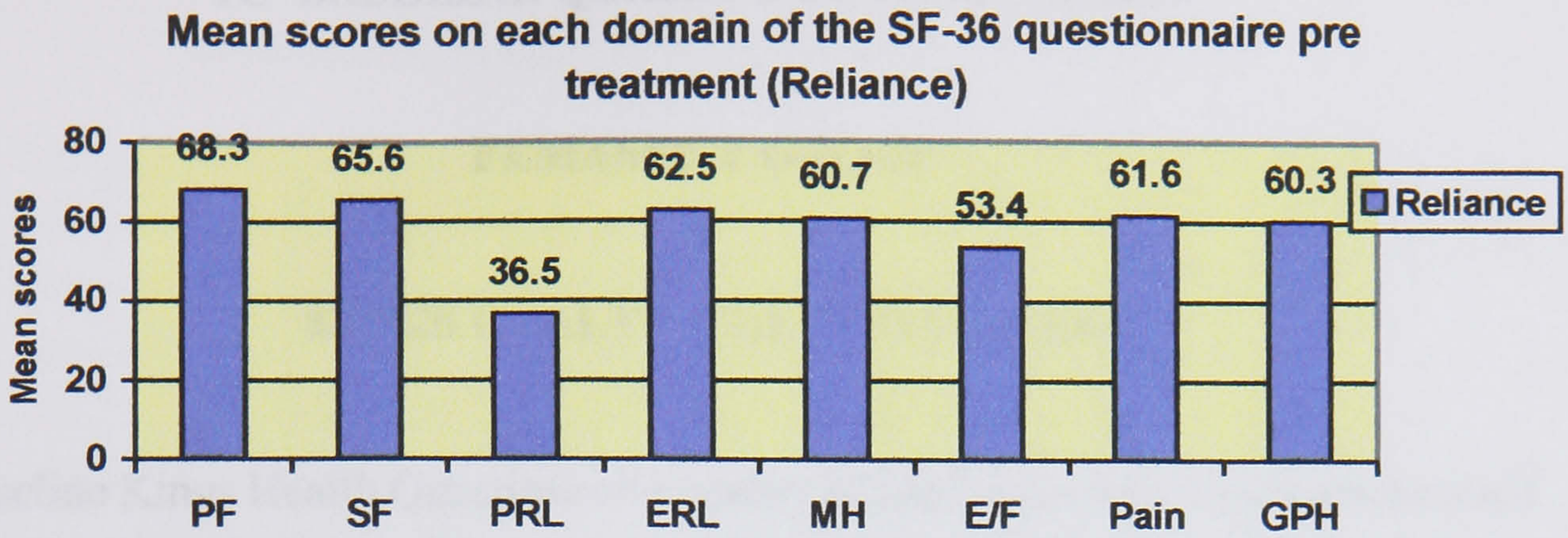


Figure 11.3 Mean baseline scores on each domain of the SF-36 questionnaire for women with GSI randomised to use the Reliance device.

The results suggest that the domain of physical role limitation was particularly influenced, and all other domains indicated moderate disruption to the quality of life of incontinent women.

1C BASELINE QUALITY OF LIFE SCORES

FEMASSIST GROUP

KINGS HEALTH QUESTIONNAIRE

The baseline Kings Health Questionnaire quality of life scores for women randomised to use the FemAssist device (n=53) are illustrated in table 11.4 and figure 11.4.

MEAN SCORES ON THE DOMAINS OF THE KINGS HEALTH QUESTIONNAIRE PRE TREATMENT									
Domains	**GHP**	**InImp**	**EL**	**RL**	**S/E**	**PersL**	**PhysL**	**SL**	**SM**
Mean	32.7	77.1	39.8	43.2	27.1	24.6	55	31	50.5
SD	25.7	25	30.43	26.21	24.7	29.76	23.04	26.76	19.8
Min	0	0	0	0	0	0	0	0	6.6
Max	80	100	100	100	83.3	100	100	100	80

Table 11.4 Summary of the mean baseline scores for women with GSI randomised to use the FemAssist device. SD = standard deviation, Min = minimum value recorded, Max = maximum recorded. {GHP = General health perception, InImp = Incontinence impact, EL = Emotional limitation, RL = Role limitation, S/E = Sleep/ energy disturbance, PersL = Personal limitation, PhysL= Physical limitation, SL = Social limitation, SM = Severity measures.}

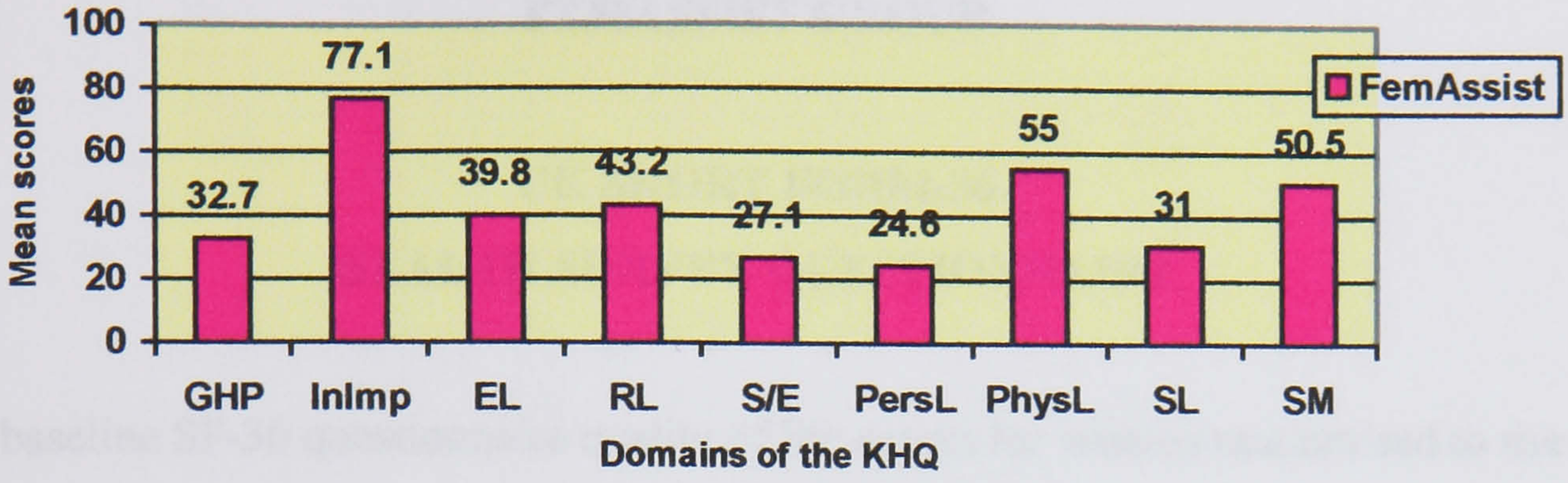


Figure 11.4 Mean baseline scores on each domain of the KHQ for women with GSI randomised to use the FemAssist device.

Women randomised to the FemAssist device showed a similar disruption to their QoL as those randomised to the Reliance. The domains of incontinence impact, physical limitation and severity measures were most influenced by incontinence. The majority of women with GSI however considered their general health to be good.

1D BASELINE QUALITY OF LIFE SCORES

FEMASSIST GROUP

UK SHORT FORM-36
HEALTH SURVEY QUESTIONNAIRE

The baseline SF-36 questionnaire quality of life scores for women randomised to use the FemAssist device (n=53) are illustrated in table 11.5 and figure 11.5.

MEAN SCORES ON THE DOMAINS OF THE UK SHORT FORM-36 PRE TREATMENT								
Domains	**PF**	**SF**	**PRL**	**ERL**	**MH**	**E/F**	**PAIN**	**GHP**
Mean	64.4	63.5	38.0	59	58.4	56.3	60.2	60
SD	12	13.12	12.75	10.37	8.39	8.16	8.28	6.85
Min	6	0	20	33	33	33	45	50
Max	88	88	66	85	75	66	80	70

Table 11.5 Summary of the mean baseline scores for women with GSI randomised to use the FemAssist device. SD = standard deviation, Min = minimum value recorded, Max = maximum recorded. [PF = physical function, SF = social function, PRL = physical role limitation, ERL = emotional role limitation, MH = mental health, E/F = energy/fatigue, GHP = general health perception]

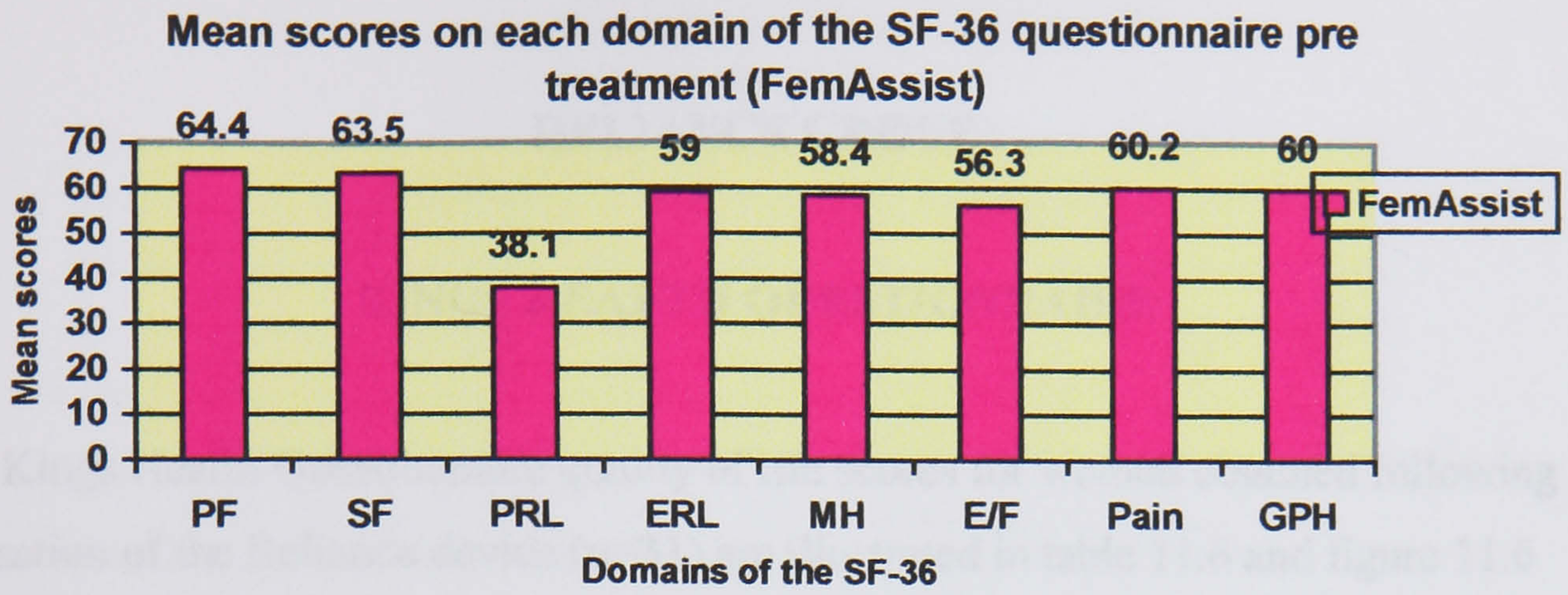


Figure 11.5 Mean baseline scores on each domain of the SF-36 questionnaire for women with GSI randomised to use the FemAssist device.

The domain of physical role limitation was most affected while all the other domains of the SF-36 questionnaire were secondarily influenced.

2A QUALITY OF LIFE SCORES AFTER TREATMENT

RELIANCE GROUP

KINGS HEALTH QUESTIONNAIRE

The Kings Health Questionnaire quality of life scores for women obtained following utilisation of the Reliance device (n=31) are illustrated in table 11.6 and figure 11.6

MEAN SCORES ON THE DOMAINS OF THE KINGS HEALTH QUESTIONNAIRE POST TREATMENT									
Domains	**GHP**	**InImp**	**EL**	**RL**	**S/E**	**PersL**	**PhysL**	**SL**	**SM**
Mean	28.3	41.3	35.5	33.8	27.3	23.2	32.3	23.6	31
SD	20.51	16.95	27	22.22	22.74	26	20.4	21.45	19.6
Min	0	0	0	0	0	0	0	0	0
Max	75	66.6	100	83.3	83.3	100	66.6	77.7	60

Table 11.6 Summary of the post treatment scores for women with GSI randomised to use the Reliance device. SD = standard deviation, Min = minimum value recorded, Max = maximum recorded. {GHP = General health perception, InImp = Incontinence impact, EL = Emotional limitation, RL = Role limitation, S/E = Sleep/ energy disturbance, PersL = Personal limitation, PhysL= Physical limitation, SL = Social limitation, SM = Severity measures.}

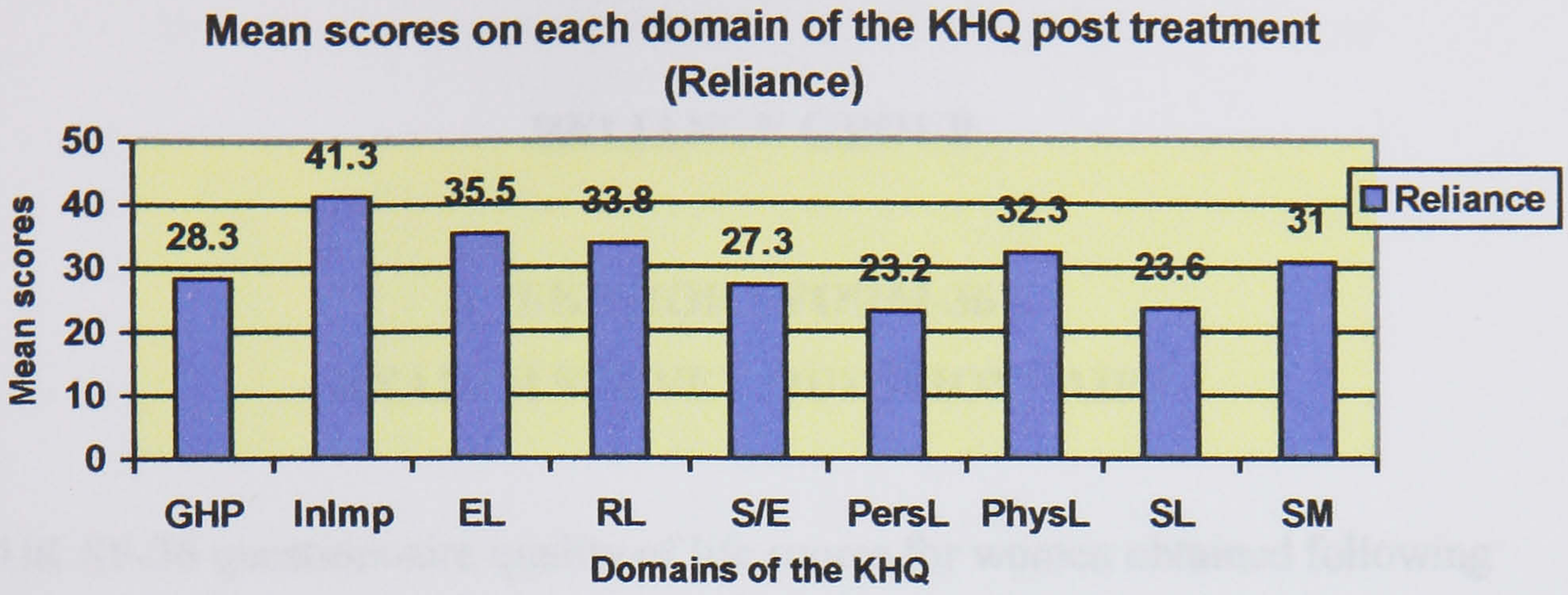


Figure 11.6 Mean post treatment scores on each domain of the KHQ for women with GSI randomised to use the Reliance device.

Following treatment with the Reliance device the domains of personal and social limitation caused the least constraint to their QoL, while the domains of incontinence impact still caused the most interference.

2B QUALITY OF LIFE SCORES AFTER TREATMENT

RELIANCE GROUP

UK SHORT FORM-36
HEALTH SURVEY QUESTIONNAIRE

The UK SF-36 questionnaire quality of life scores for women obtained following utilisation of the Reliance device (n=31) are illustrated in table 11.7 and figure 11.7

MEAN SCORES ON THE DOMAINS OF THE UK SHORT FORM-36 POST TREATMENT								
Domain	**PF**	**SF**	**PRL**	**ERL**	**MH**	**E/F**	**PAIN**	**GHP**
Mean	88.9	85.7	67.5	61.9	60.1	54.6	62.2	60.8
SD	3.76	5.85	7.09	5.42	5.58	6.41	6.47	4.84
Min	80	75	59	50	50	43	50	50
Max	97	100	89	74	66	66	80	66

Table 11.7 Summary of the mean post treatment scores for women with GSI randomised to use the Reliance device. SD = standard deviation, Min = minimum value recorded, Max = maximum recorded. [PF = physical function, SF = social function, PRL = physical role limitation, ERL = emotional role limitation, MH = mental health, E/F = energy/fatigue, GHP = general health perception]

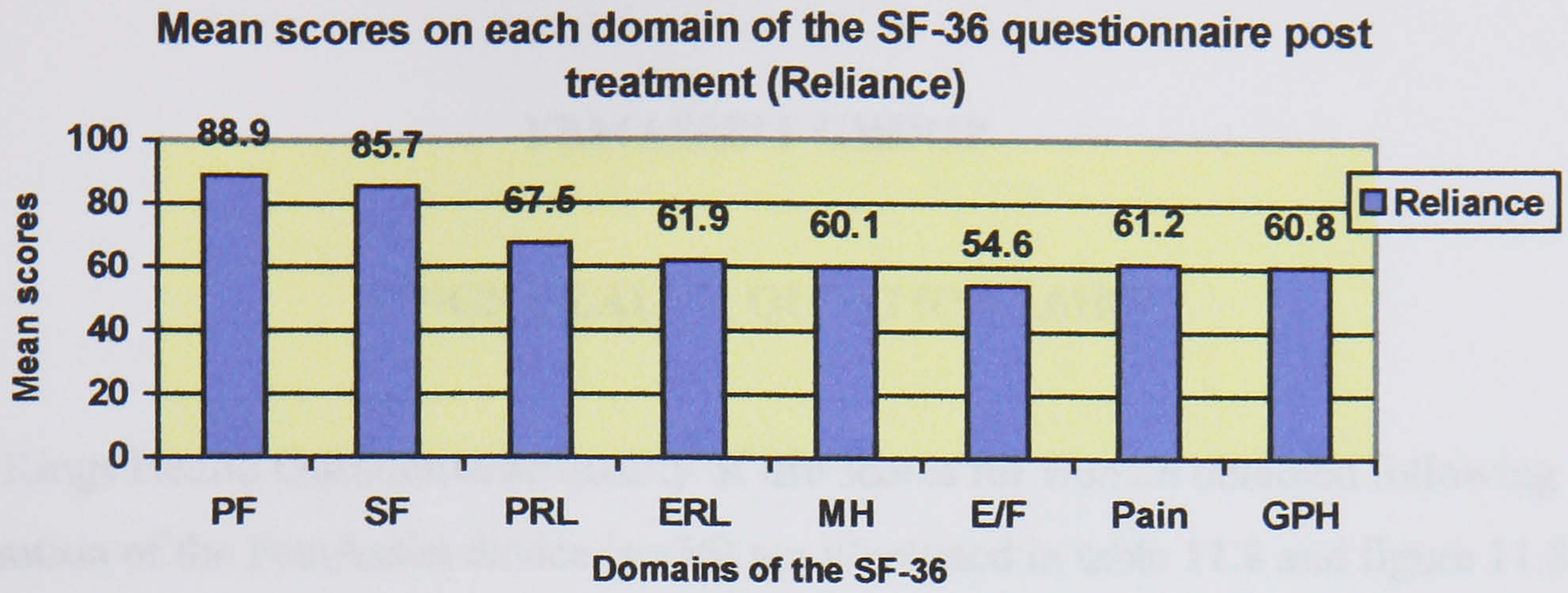


Figure 11.7 Mean post treatment scores on each domain of the SF-36 questionnaire for women with GSI randomised to use the Reliance device.

The domains of physical and social function on the SF-36 questionnaire caused the least disruption to their QoL while the other domains were not as well improved.

2C QUALITY OF LIFE SCORES AFTER TREATMENT

FEMASSIST GROUP

KINGS HEALTH QUESTIONNAIRE

The Kings Health Questionnaire quality of life scores for women obtained following utilisation of the FemAssist device (n=36) are illustrated in table 11.8 and figure 11.8

MEAN SCORES ON THE DOMAINS OF THE KINGS HEALTH QUESTIONNAIRE POST TREATMENT									
Domains	**GHP**	**InImp**	**EL**	**RL**	**S/E**	**PersL**	**PhysL**	**SL**	**SM**
Mean	31.6	48.2	34.9	41.2	22.1	24.2	17.1	22.5	29.1
SD	18.6	19.1	33	15.3	19.6	22	19.45	23	16.9
Min	0	0	0	0	0	0	0	0	0
Max	80	77	90	85	88	100	100	77	85

Table 11.8 Summary of the post treatment scores for women with GSI randomised to use the FemAssist device. SD = standard deviation, Min = minimum value recorded, Max = maximum recorded. {GHP = General health perception, InImp = Incontinence impact, EL = Emotional limitation, RL = Role limitation, S/E = Sleep/ energy disturbance, PersL = Personal limitation, PhysL= Physical limitation, SL = Social limitation, SM = Severity measures.}

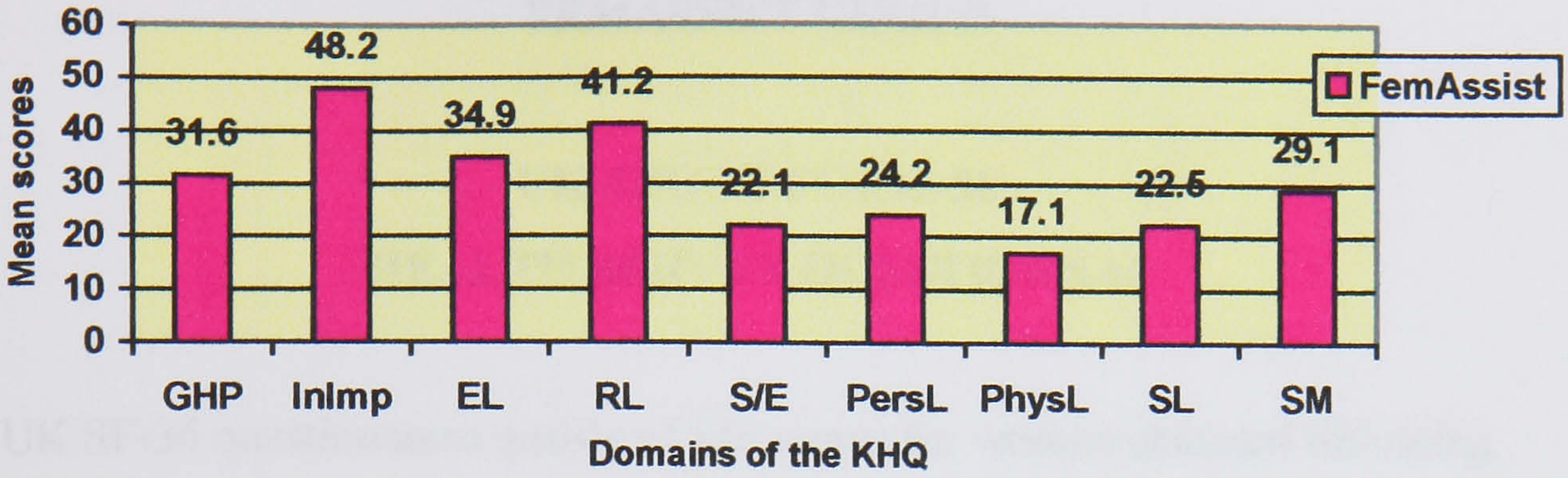


Figure 11.8 Mean post treatment scores on each domain of the KHQ for women with GSI randomised to use the FemAssist device.

The domains of physical and social limitation on the Kings Health Questionnaire caused the least disruption to their QoL while the other domains were not as well improved. The domain of incontinence impact still caused the most problem for incontinent women using the FemAssist device similar to the findings in women using the Reliance.

2D QUALITY OF LIFE SCORES AFTER TREATMENT

FEMASSIST GROUP

UK SHORT FORM-36
HEALTH SURVEY QUESTIONNAI

The UK SF-36 questionnaire quality of life scores for women obtained following utilisation of the FemAssist device (n=36) are illustrated in table 11.9 and figure 11.9.

MEAN SCORES ON THE DOMAINS OF THE UK SHORT FORM-36 POST TREATMENT								
Domains	**PF**	**SF**	**PRL**	**ERL**	**MH**	**E/F**	**PAIN**	**GHP**
Mean	84	83.6	71.9	61.9	62.7	78.2	62.5	59.5
SD	5.88	6.15	13.7	3.97	3.02	10.4	5.03	5.06
Min	66	66	6	55	60	42	50	50
Max	90	99	88	66	66	100	77	66

Table 11.9 Summary of the mean post treatment scores for women with GSI randomised to use the FemAssist device. SD = standard deviation, Min = minimum value recorded, Max = maximum recorded. [PF = physical function, SF = social function, PRL = physical role limitation, ERL = emotional role limitation, MH = mental health, E/F = energy/fatigue, GHP = general health perception]

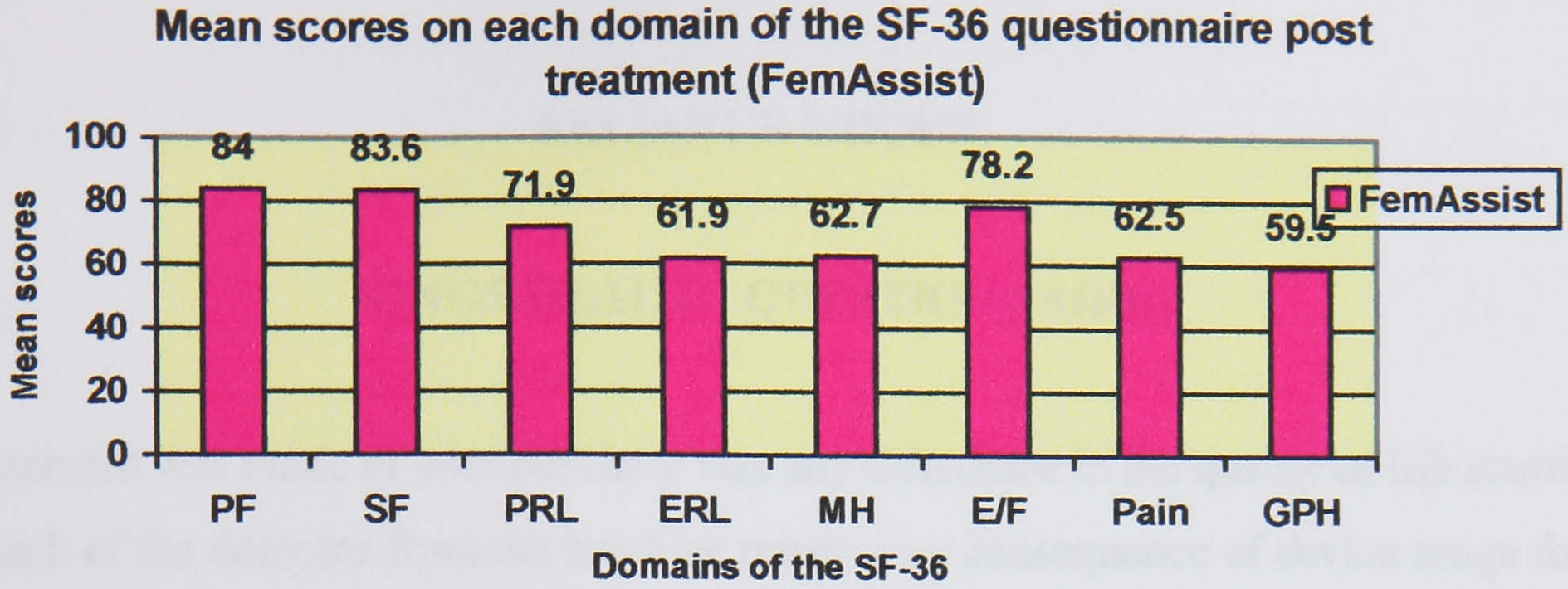


Figure 11.9 Mean post treatment scores on each domain of the SF-36 questionnaire for women with GSI randomised to use the FemAssist device.

After treatment with the FemAssist device the SF 36 domains of physical and social function were least influenced and the other domains not as well controlled.

3A COMPARISON OF PRE AND POST TREATMENT SCORES

RELIANCE GROUP

KINGS HEALTH QUESTIONNAIRE

Assessment was made of whether there was any difference in the quality of life scores for each of the domains from the baseline results as a consequence of device usage for those completing the trial. Analysis was performed for each domain of the SF36 and the KH Q for each of the groups, Reliance and FemAssist. Figures 11.10 and 11.11 and table 11.10 summarises the estimates of the groups means and paired differences in the measures between the scores obtained using the KHQ questionnaire at baseline and 6 month post treatment with the Reliance device (n=31 pairs).

MEAN SCORES ON THE DOMAINS OF THE KINGS HEALTH QUESTIONNAIREPRE AND POST TREATMENT									
Domains	**GHP**	**InImp**	**EL**	**RL**	**S/E**	**PersL**	**PhysL**	**SL**	**SM**
Baseline	28.9	75.9	40.8	51	26.7	28.8	58.5	34.4	53.5
6 month	28.3	41.3	35.5	33.8	27.3	23.2	32.3	23.6	31
Paired differences (N= 31, paired t-test statistics)									
Mean	0.61	34.6	5.21	17.2	-0.5	5.6	26.3	13.8	22.6
SD	11.7	21.2	16.1	15.3	17.9	20.7	21.7	18.68	16.6
SEM	2.03	3.7	2.8	2.7	3.1	3.6	3.8	4.17	2.9
2-tail sig	0.77	**0.000**	0.072	**0.000**	0.87	0.133	**0.000**	**0.004**	**0.000**
95% CI	-3.5, 4.8	27.1, 42.1	-0.49, 10.92	11.7, 22.6	-6.8, 5.8	-1.8, 12.9	18.6, 34	9.6, 16	16.7, 28.5

Table 11.10 Summary of the estimates of the groups means and differences in the measures between the scores obtained using the KHQ at baseline and 6 month post Reliance treatment. SD = standard deviation, SEM = standard error of mean, 95% CI = 95% confidence interval. {GHP = General health perception, InImp = Incontinence impact, EL = Emotional limitation, RL = Role limitation, S/E = Sleep/ energy disturbance, PersL = Personal limitation, PhysL= Physical limitation, SL = Social limitation, SM = Severity measures.}

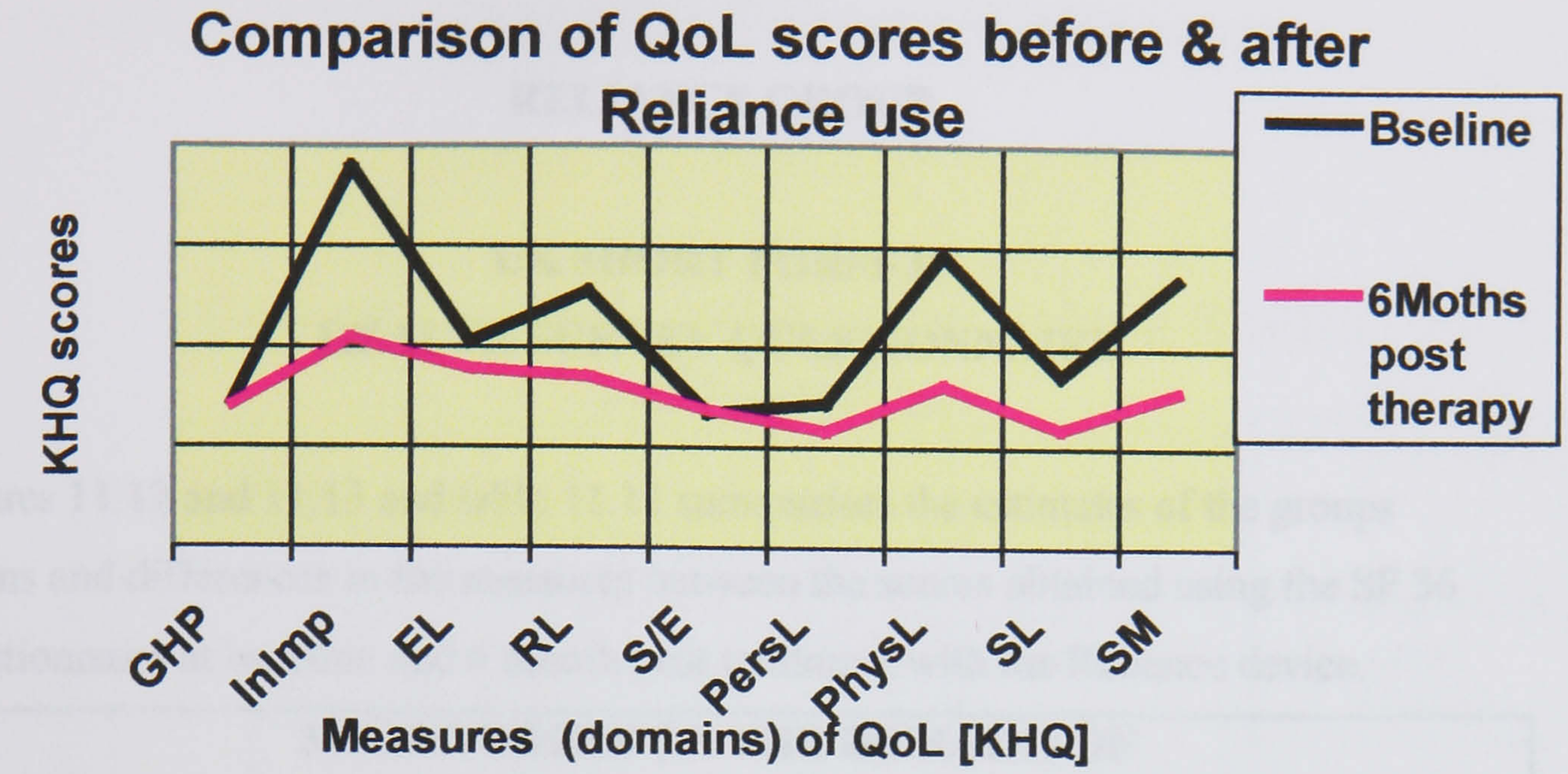


Figure 11.10 Comparison of measures of QoL (KHQ) at baseline and after 6 months therapy with the Reliance device. Lines join the means. Lower scores represent better QoL.

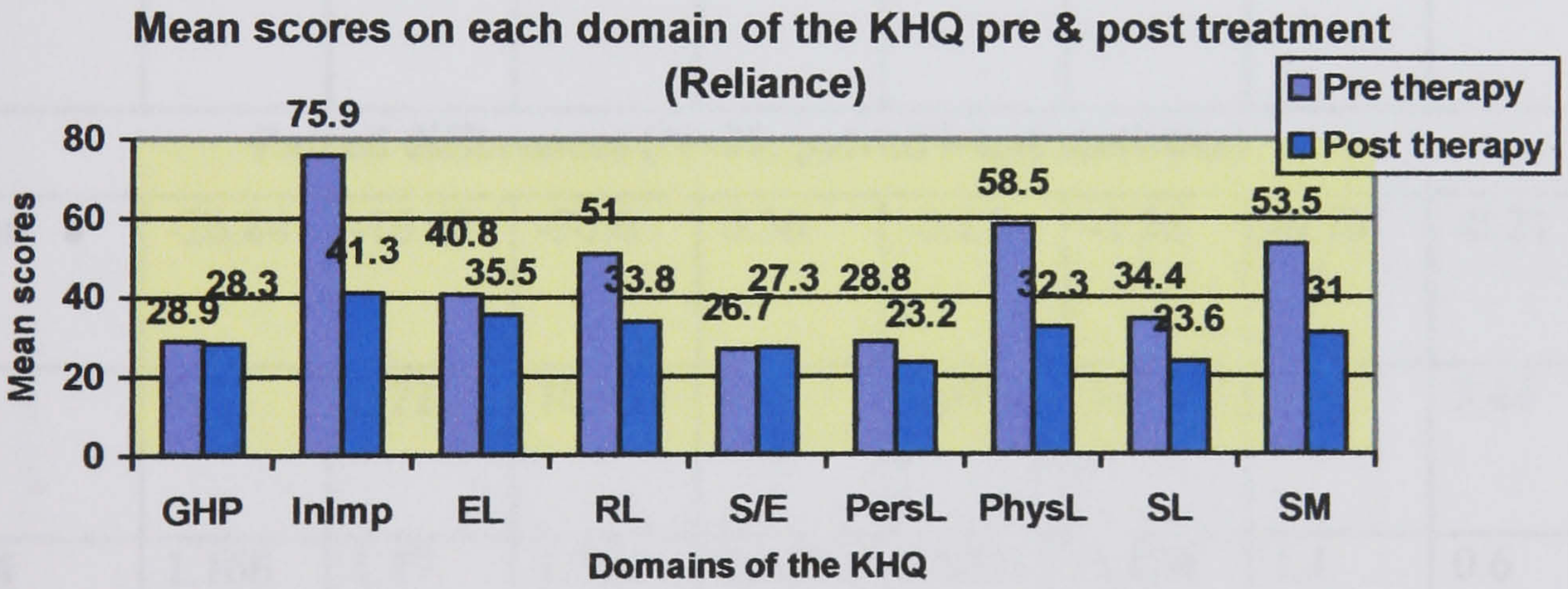


Figure 11.11 Mean pre and post treatment scores on each domain of the KHQ.

Greatest changes in the quality of life of women with GSI using the Reliance device were observed in the domains of incontinence impact, role and physical limitation. These modifications were striking and considered clinically significant. There was not much alteration in their general health perception and energy levels however. The remaining measures of QoL as assessed on this questionnaire were also influenced in a favourable direction.

3B COMPARISON OF PRE AND POST TREATMENT SCORES

RELIANCE GROUP

UK SHORT FORM-36
HEALTH SURVEY QUESTIONNAIRE

Figures 11.12 and 11.13 and table 11.11 summarises the estimates of the groups means and differences in the measures between the scores obtained using the SF 36 questionnaire at baseline and 6 month post treatment with the Reliance device.

MEAN SCORES ON THE DOMAINS OF THE UK SHORT FORM-36 QUESTIONNAIRE PRE AND POST TREATMENT								
Domains	**PF**	**SF**	**PRL**	**ERL**	**MH**	**E/F**	**PAIN**	**GHP**
Baseline	68.3	68.9	36.5	62.5	60.7	53.4	61.6	60.3
6 month	88.9	85.7	67.8	61.9	60.1	54.6	62.2	60.8
Paired differences (N=31, paired t-test statistics)								
Mean	-20.84	-16.69	-30.6	0.36	-0.27	-1.36	-0.76	-0.21
SD	6.7	6.72	10.13	4.8	4.57	4.73	6.26	3.44
SEM	1.166	1.17	1.764	0.837	0.797	0.824	1.1	0.6
2-tail sig	**0.000**	**0.000**	**0.000**	0.67	0.73	0.11	0.5	0.73
95% CI	-23.22, -18.47	-19, -14.3	-34.2, -27	-1.34, 2.07	-1.9, 1.35	-3, 0.32	-2.98, 1.46	-1.43, 1.01

Table 11.11 Summary of the mean SF-36 scores for women with GSI randomised to use the Reliance device on entry to the study and after 6 months of device utilisation. SD = standard deviation, SEM = standard error of mean. [PF = physical function, SF

= social function, PRL = physical role limitation, ERL = emotional role limitation, MH = mental health, E/F = energy/fatigue, GHP = general health perception.

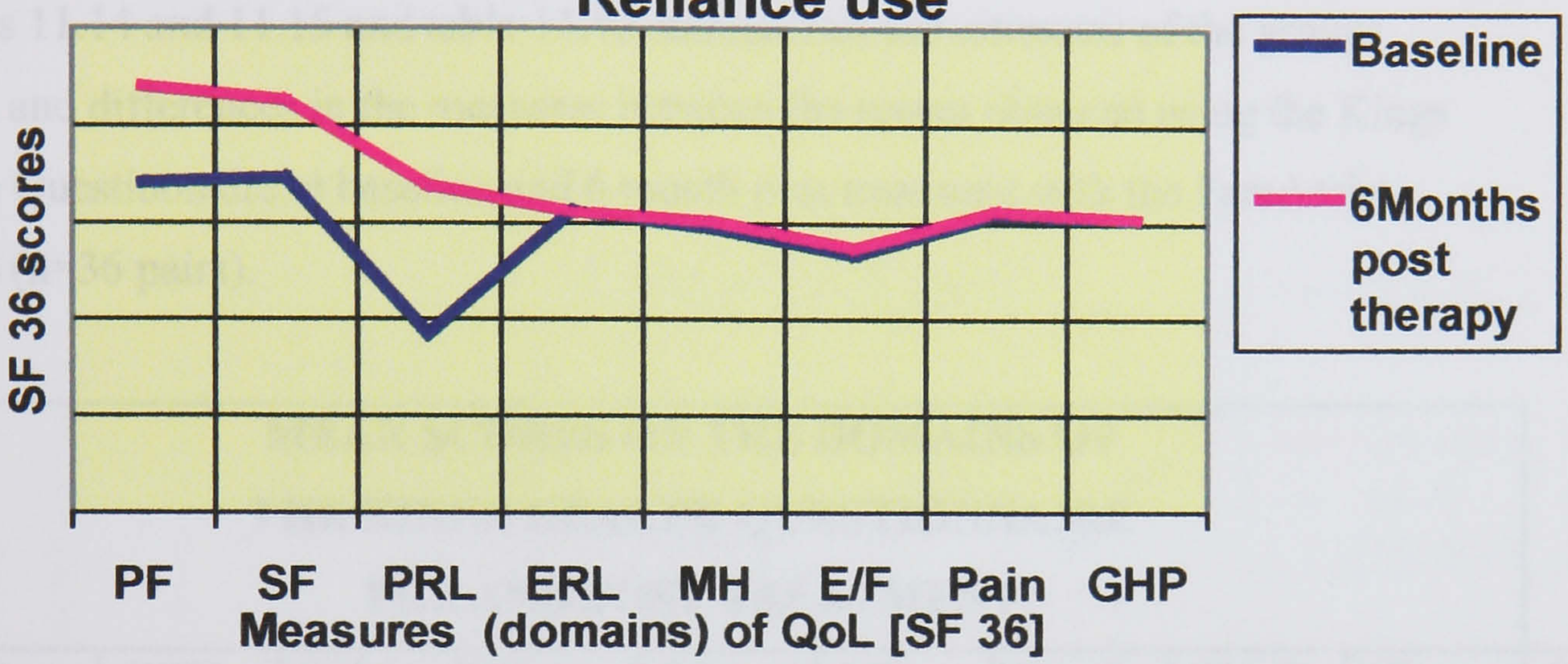


Figure 11.12 Comparison of measures of QoL (SF 36) at baseline and after 6 months of therapy with the Reliance device. Lines join the means. Higher scores represent better QoL.

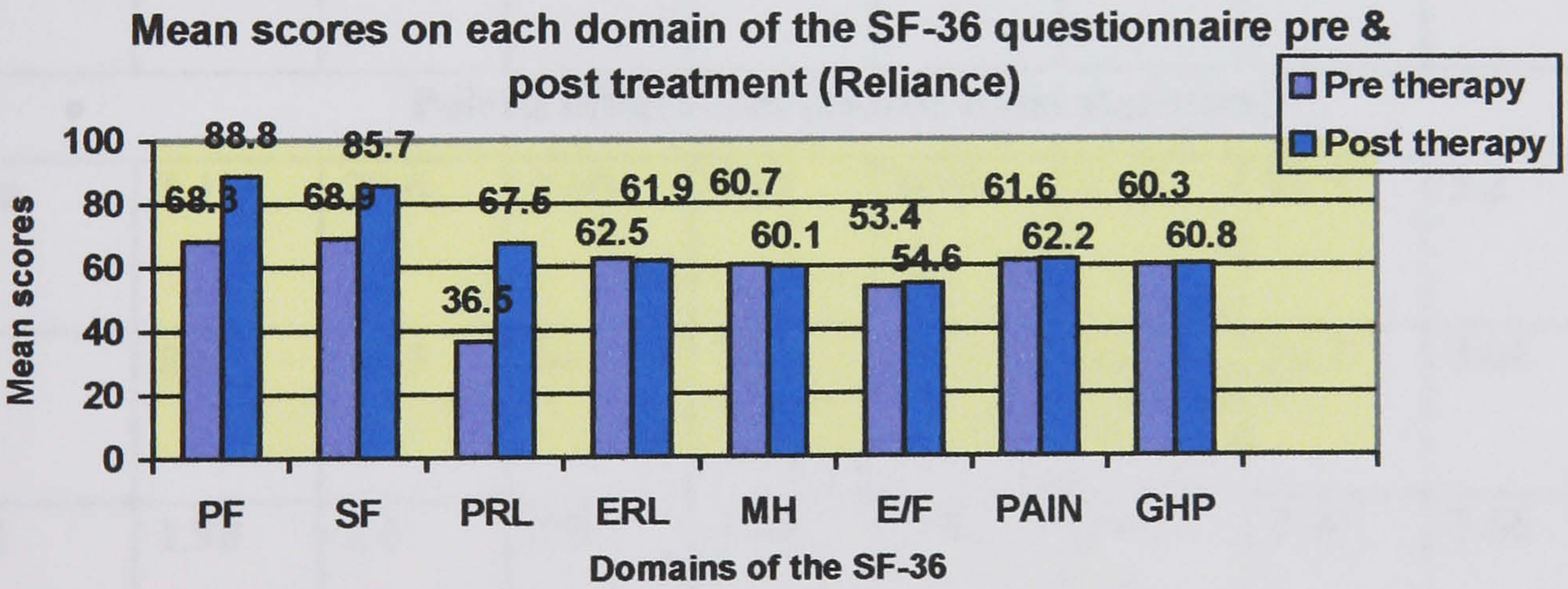


Figure 11.13 Comparison of mean pre and post treatment scores on each domain of the SF-36 questionnaire for women with GSI randomised to use the Reliance device.

As a consequence of Reliance device utilisation the greatest changes recorded on the SF-36 questionnaire arose in the domains of physical role limitation and in physical and social function.

3C COMPARISON OF PRE AND POST TREATMENT SCORES

FEMASSIST GROUP

KINGS HEALTH QUESTIONNAIRE

Figures 11.14 and 11.15 and table 11.12 summarises the estimates of the groups means and differences in the measures between the scores obtained using the Kings Health Questionnaire at baseline and 6 month post treatment with the FemAssist device (n=36 pairs).

MEAN SCORES ON THE DOMAINS OF THE KINGS HEALTH QUESTIONNAIRE PRE AND POST TREATMENT									
Domains	**GHP**	**InImp**	**EL**	**RL**	**S/E**	**PersL**	**PhysL**	**SL**	**SM**
Baseline	30.4	75.2	42.1	38.2	33	27	49.1	32.2	55.3
6 month	31.6	48.2	34.9	41.2	22.1	24.2	17.1	22.5	29.1
Paired differences (paired t-test statistics)									
Mean	1.11	29.6	4.66	10.1	0.94	3.36	22.3	5.2	18.6
SD	8.6	12.5	14.1	12.2	22.1	18.1	21.2	3.04	14.2
SEM	1.98	2.6	2.9	3.45	3.81	3.55	2.98	3.66	3.2
2-tail sig	0.68	**0.000**	0.56	0.081	**0.04**	0.754	**0.000**	**0.03**	**0.000**
95% CI	0.2, 3.66	26.7, 37.9	1.22, 8.59	13.1, 0.55	6.3, 0.26	1.6, 7.2	19.5, 28.4	13.1, 3.22	14.6, 24.8

Table 11.12 Summary of the estimates of the groups means and differences in the measures between the scores obtained using the KHQ at baseline and 6 month post

FemAssist treatment. SD = standard deviation, SEM = standard error of mean, 95% CI = 95% confidence interval. {GHP = General health perception, InImp = Incontinence impact, EL = Emotional limitation, RL = Role limitation, S/E = Sleep/ energy disturbance, PersL = Personal limitation, PhysL= Physical limitation, SL = Social limitation, SM = Severity measures.}

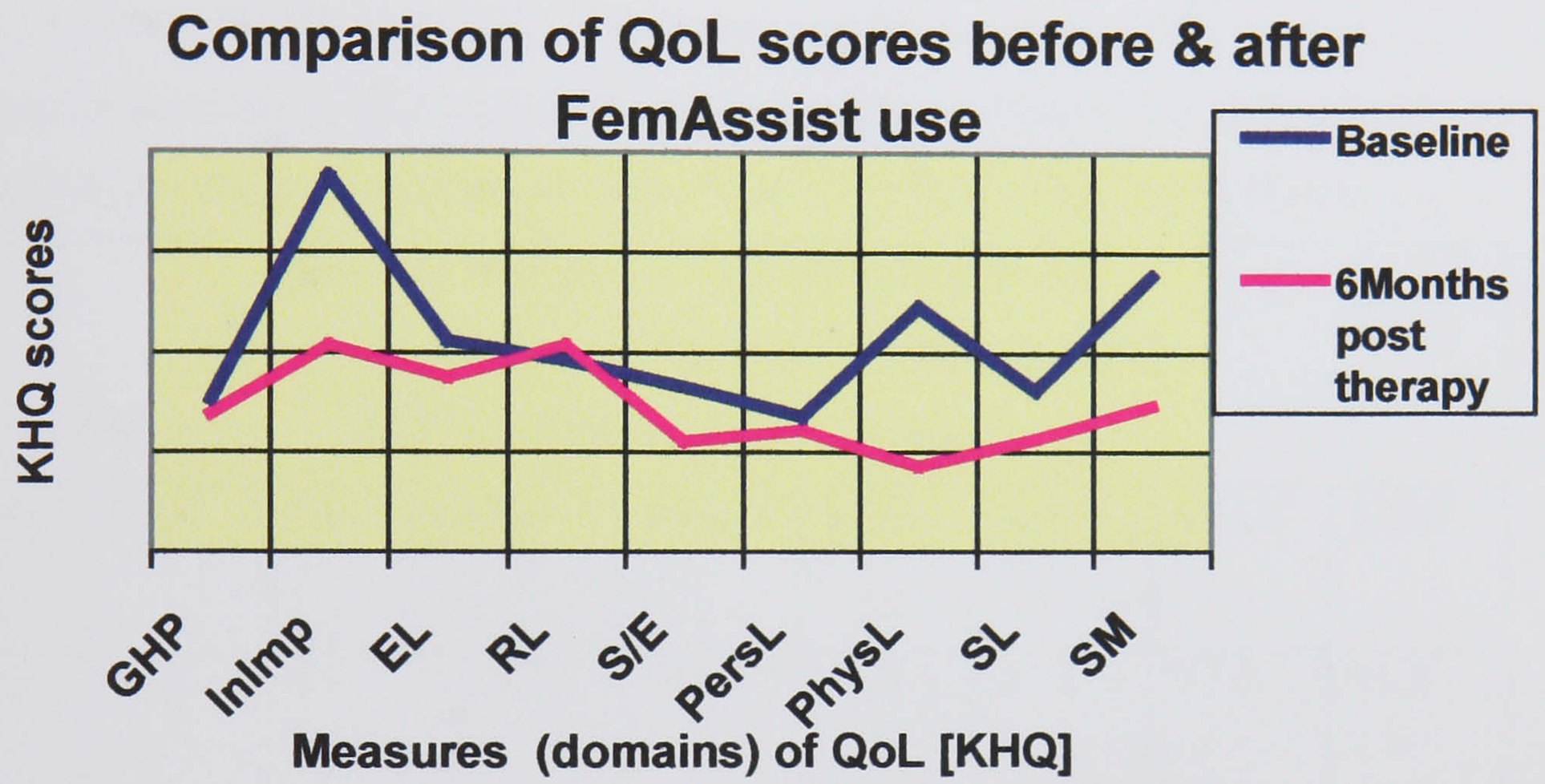


Figure 11.14 Comparison of measures of QoL (KHQ) at baseline and after 6 months therapy with the FemAssist device. Lines join the means. Lower scores represent better QoL.

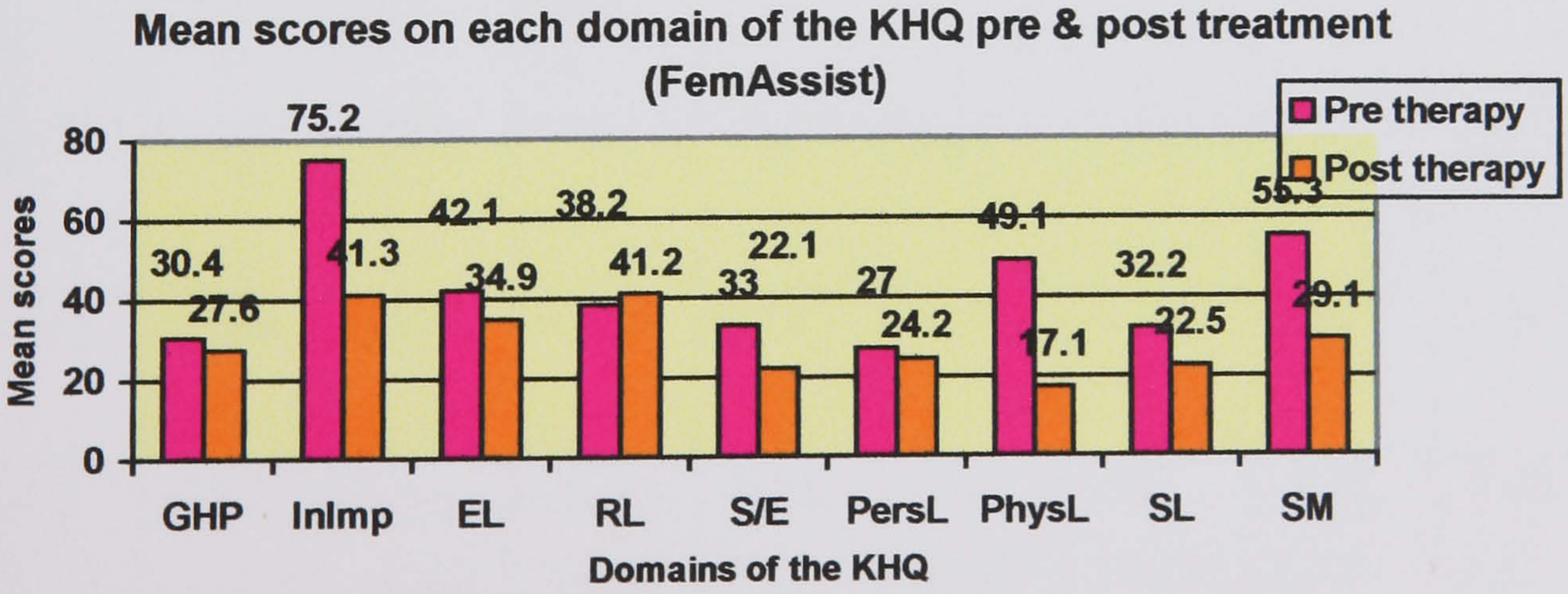


Figure 11.15 Comparison of mean pre and post treatment scores on each domain of the KHQ for women with GSI randomised to use the FemAssist device.

Greatest changes in the quality of life of women with GSI using the FemAssist device were observed in the domains of incontinence impact, physical limitation and severity measures of incontinence. These modifications were striking and considered clinically significant. There was not much alteration in their general health perception, emotional and personal limitation and energy levels however. The remaining measures of QoL as assessed on this questionnaire were also influenced in a favourable direction, albeit moderately.

3D COMPARISON OF PRE AND POST TREATMENT SCORES

FEMASSIST GROUP

UK SHORT FORM-36
HEALTH SURVEY QUESTIONNAIRE

Figures 11.16 and 11.17 and table 11.13 summarises the estimates of the groups means and differences in the measures between the scores obtained using the SF-36 questionnaire at baseline and 6 month post treatment with the FemAssist device.

MEAN SCORES ON THE DOMAINS OF THE UK SHORT FORN-36 QUESTIONNAIRE PRE AND POST TREATMENT								
Domains	**PF**	**SF**	**PRL**	**ERL**	**MH**	**E/F**	**PAIN**	**GHP**
Baseline	62.1	65	36.5	61	59.8	55.8	57.9	61.8
6 month	84	83.6	71.9	61.9	62.7	78.2	62.5	59.5
Paired differences (N=36, paired t-test statistics)								
Mean	-18.39	-19.93	-35.6	3.5	-4.29	-22.54	2.61	0.56
SD	8.84	9.56	16.19	10.92	8.97	10.4	8.9	8
SEM	1.538	1.666	2.81	1.87	1.53	18.2	1.55	1.37
2-tail sig	**0.000**	**0.000**	**0.000**	0.71	0.19	0.23	0.10	0.69
95% CI	-21.52, -15.26	-23.3, -16.54	-41.38, -29.86	-0.31, 7.31	-7.42, -1.16	-59, 14.62	-0.55, 5.76	-2.23, 3.35

Table 11.13 Summary of the mean SF-36 scores for women with GSI randomised to use the FemAssist device on entry to the study and after 6 months of device

utilisation. SD = standard deviation, Min = minimum value recorded, Max = maximum recorded. [PF = physical function, SF = social function, PRL = physical role limitation, ERL = emotional role limitation, MH = mental health, E/F = energy/fatigue, GHP = general health perception]

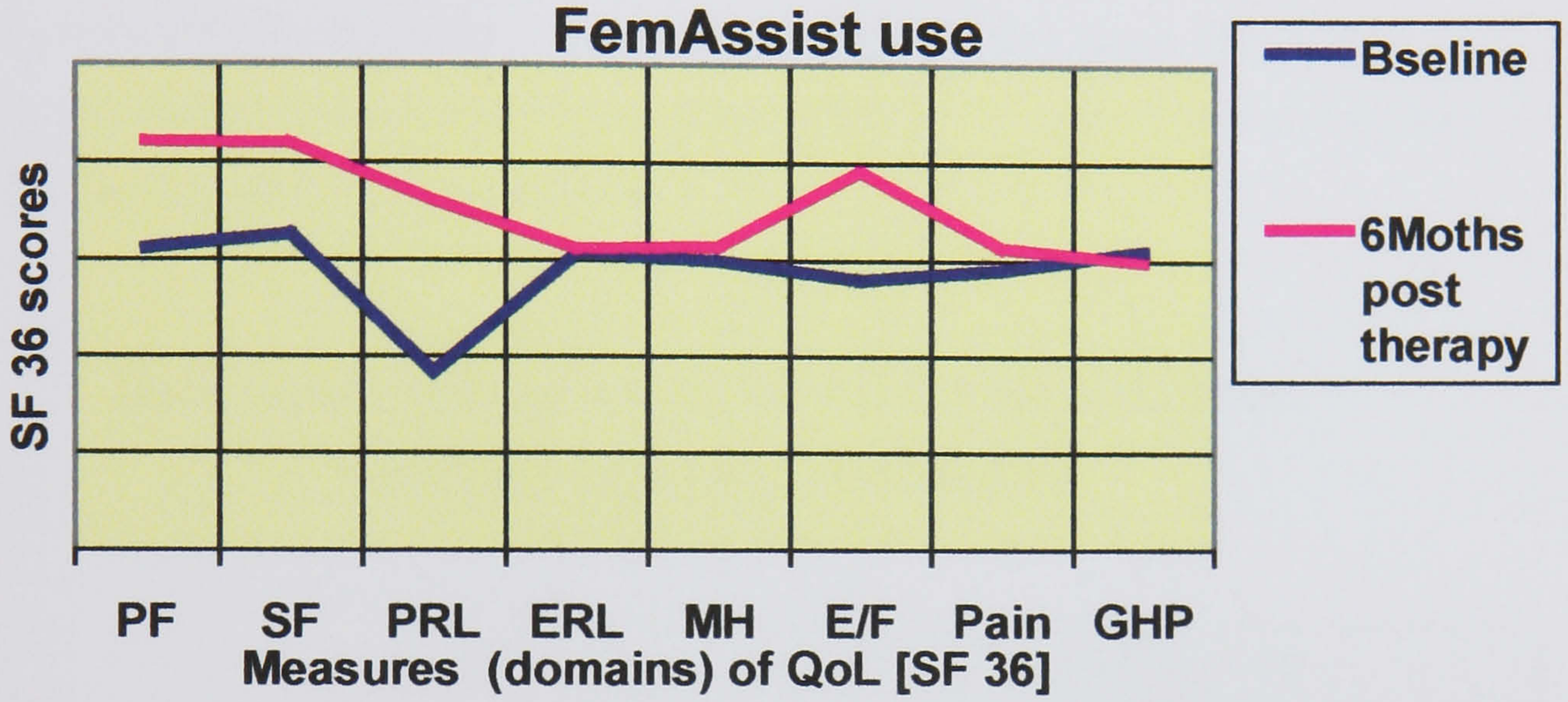


Figure 11.16 Comparison of measures of QoL (SF 36) at baseline and after 6 months therapy with the FemAssist device. Lines join the means. Higher scores represent better QoL.

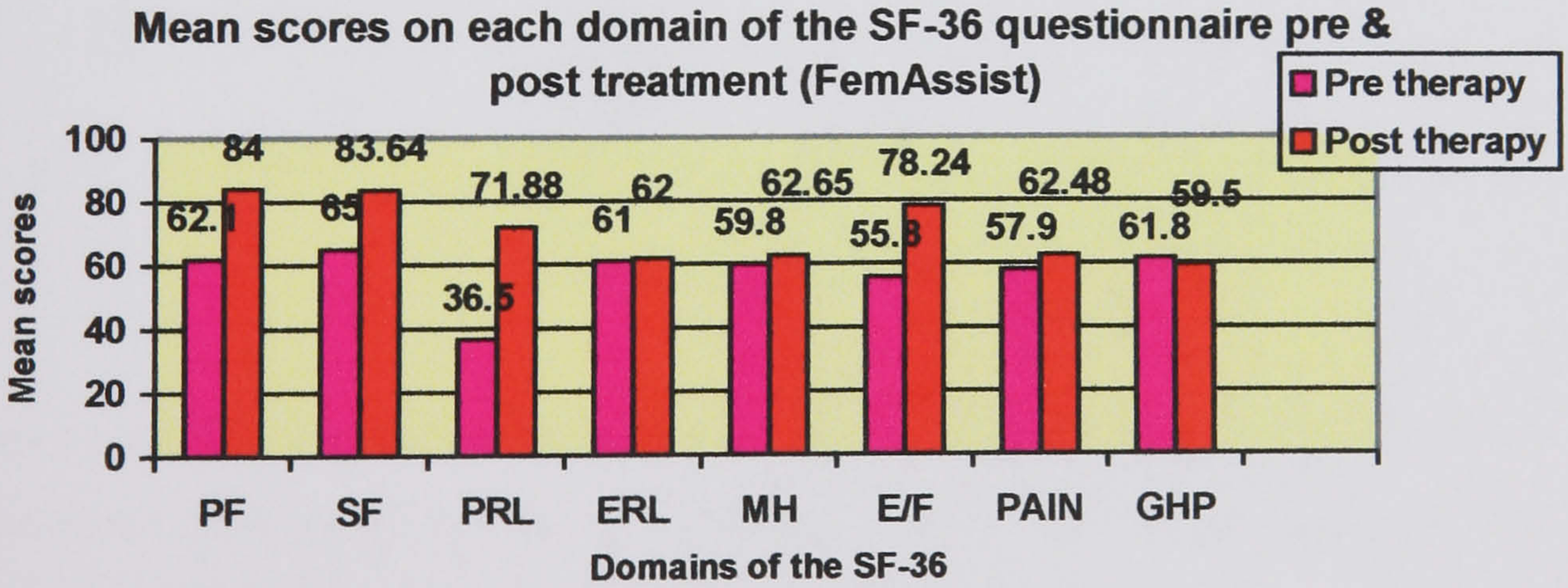


Figure 11.17 Comparison of mean pre and post treatment scores on each domain of the SF-36 questionnaire for women with GSI randomised to use the FemAssist device.

Following treatment with the FemAssist device the greatest changes were observed in the domains of physical role limitation and physical and social functioning. Energy and sleep levels seemed to be more favourable but the remaining measures of quality of life were little influenced.

4 BASELINE DATA COMPARED WITH POPULATION NORMS AND PATIENTS WITH LONG STANDING ILLNESS

UK SHORT FORM 36
HEALTH SURVEY QUESTIONNAIRE

The baseline SF-36 scores for women receiving the Reliance and FemAssist devices were compared with the mean SF-36 scores for the general population (Figures 11.18 & 11.19). Population norms for the dimensions of the SF-36 were obtained from the Oxford Regional Healthy Lifestyle Survey [1].

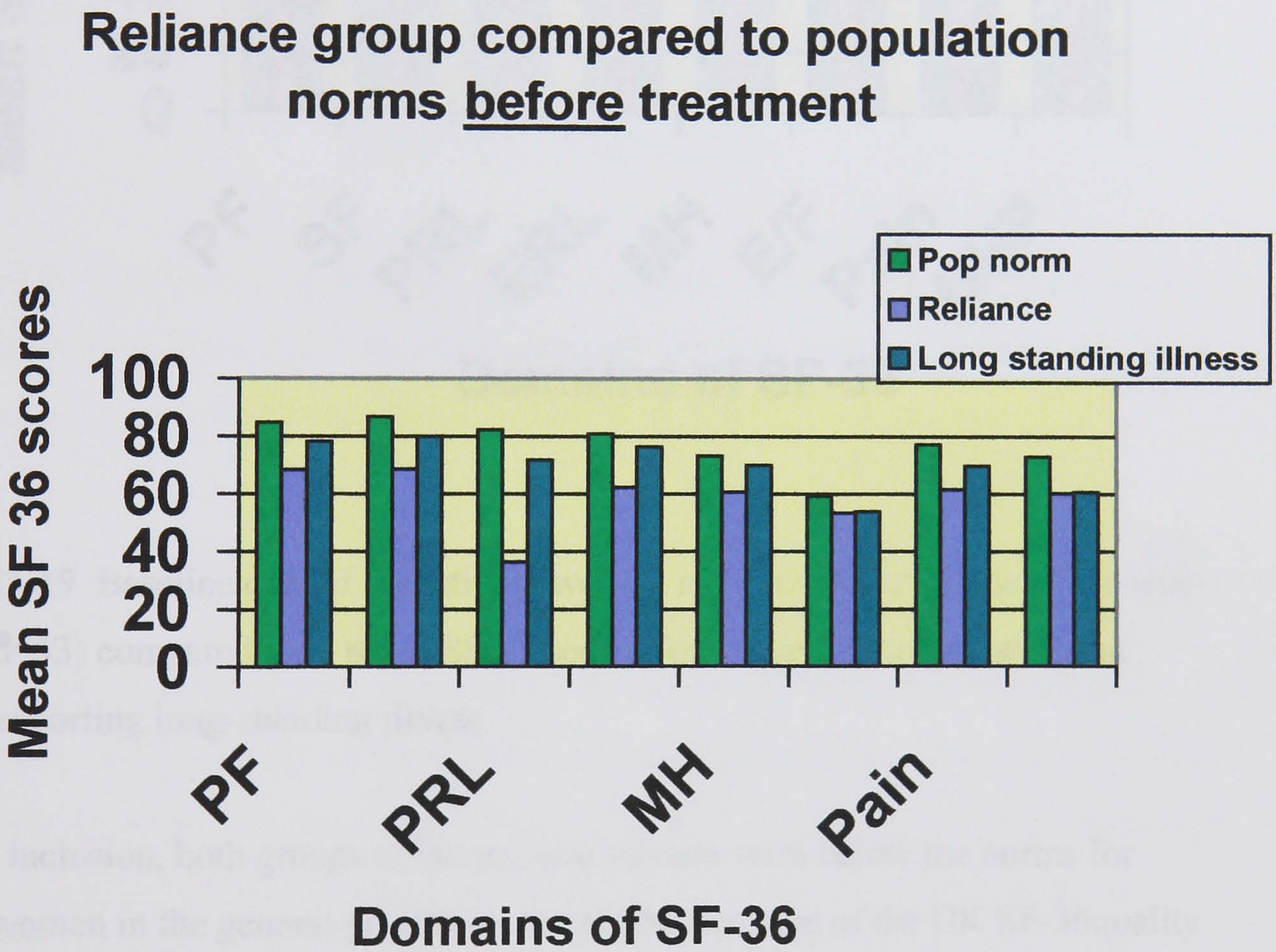


Figure 11.18 Baseline data of incontinent women randomised to use the Reliance device (n=48) compared with mean SF-36 scores for the general population and patients reporting long-standing illness.

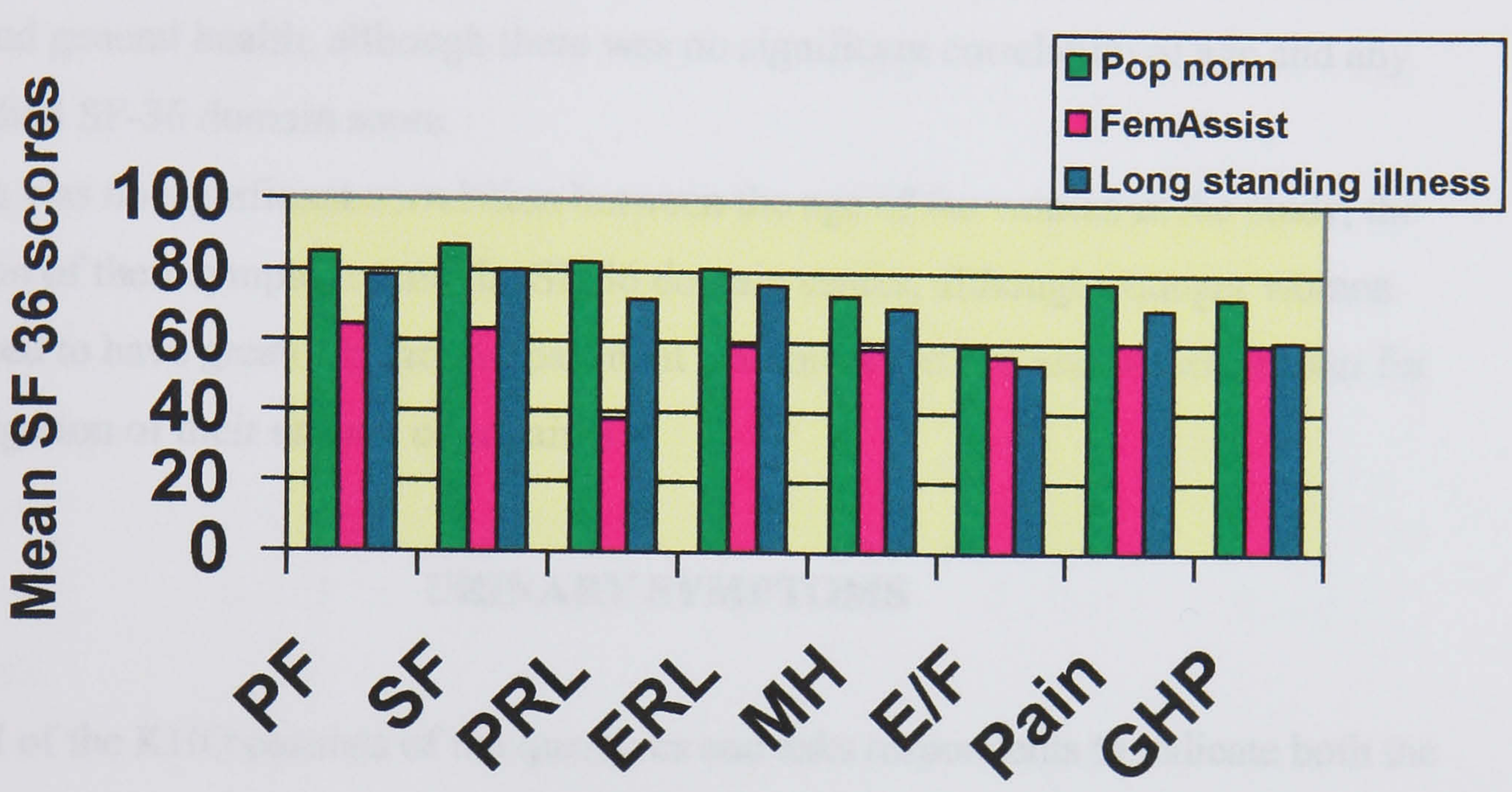


Figure 11.19 Baseline data of incontinent women randomised to use the FemAssist device (n=53) compared with mean SF-36 scores for the general population and patients reporting long-standing illness.

At study inclusion, both groups of incontinent women were below the norms for healthy women in the general population for all the domains of the UK SF-36quality of life questionnaire. In particular the domains of general health perception and role limitation were less favourable possibly because of emotional problems and physical restrictions. Women with GSI had similar scores to those with long-standing illness in the domains of general health perception, energy and fatigue levels. Women with long-standing illness suffer more and have greater levels of pain compared to women with urinary incontinence although social function and emotional role limitations are greater for women with urinary incontinence. However incontinent women recorded

worse quality of life on the remaining measures than women with long standing illness.

Age

Compared to general population scores women less than 45 years of age have lower scores in the domains of physical function, social function, physical role limitations, pain and general health, although there was no significant correlation of age and any individual SF-36 domain score.

There was no significant correlation between the age of the women in the study, the duration of their symptoms and the SF-36 domain scores, although younger women appeared to have greater overall impairment than older women and present earlier for investigation of their urinary complaints.

URINARY SYMPTOMS

Part III of the KHQ consists of ten questions and asks respondents to indicate both the urinary symptoms from which they are suffering and how bothersome they are. Both groups were comparable at baseline.

In table 11.14, the mean urinary symptom scores to each of the questions for women with GSI are shown (aggregated data). The table also illustrates the mean scores before and after treatment with each device. Multiple stepwise linear regression analysis was used to determine the effect of individual urinary symptoms on the total KHQ score. Urge incontinence (multiple R = 0.436; T = 4.392, frequency (multiple R = 0.498; T = 4.831), stress incontinence (multiple R = 0.601; T= 4.821, nocturia (multiple R = 0.615, T = 4.262) and urgency (multiple R = 0.649; T = 3.526) all significantly influenced the total KHQ score ($p<0.01$), whereas other symptoms in the questionnaire did not.

URINARY SYMPTOM SCORES RECORDED ON THE KHQ					
	Aggregated baseline data	**RELIANCE (N=31)**		**FEMASSIST (N=36)**	
		Baseline	**Post therapy**	**Baseline**	**Post therapy**
Symptom					
Frequency	1.78(3.0)	1.69(3.0)	1.55(2.0)	1.65(3.0)	1.59(2.0)
Urgency	1.89(3.0)	1.71(3.0)	1.86(3.0)	1.76(3.0)	1.83(3.0)
Urge Incontinence	1.86(3.0)	1.81(3.0)	1.79(3.0)	1.55(3.0)	1.62(3.0)
Nocturia	1.6(2.0)	1.59(2.0)	1.66(2.0)	1.66(2.0)	1.71(2.0)
Nocturnal Enuresis	0.24(0.0)	0.15(0.0)	0.18(0.0)	0.19(0.0)	0.21(0.0)
Stress Incontinence	2.4(3.0)	2.5(3.0)	1.5(1.0)	2.3(3.0)	1.52(1.0)
Intercourse Incontinence	0.67(0.0)	0.56(0.0)	0.7(0.0)	0.62(0.0)	0.65(0.0)
Recurrent UTIs	0.35(0.0)	0.15(0.0)	0.19(0.0)	0.2(0.0)	0.22(0.0)
Bladder pain	0.30(0.0)	0.17(0.0)	0.19(0.0)	0.22(0.0)	0.19(0.0)

Table 11.14 Scores on Part III of the KHQ (Symptom analysis) for the aggregated data and before and after treatment in both groups. Numbers represent the mean score and the number in brackets the modal score. Score = 0 (i.e. not a problem); Score 1 = bothered a little; Score 2 = bothered moderately; Score 3 = bothered a lot.

5A COMPARISON OF POST TREATMENT SCORES WITH POPULATION NORMS

RELIANCE GROUP

UK SHORT FORM 36

HEALTH SURVEY QUESTIONNAIRE

The 6 months post-treatment UK SF-36 scores for women using the Reliance device were compared with the scores obtained at study inclusion and is illustrated in the bar chart below (Figure 11.20 and 11.21)

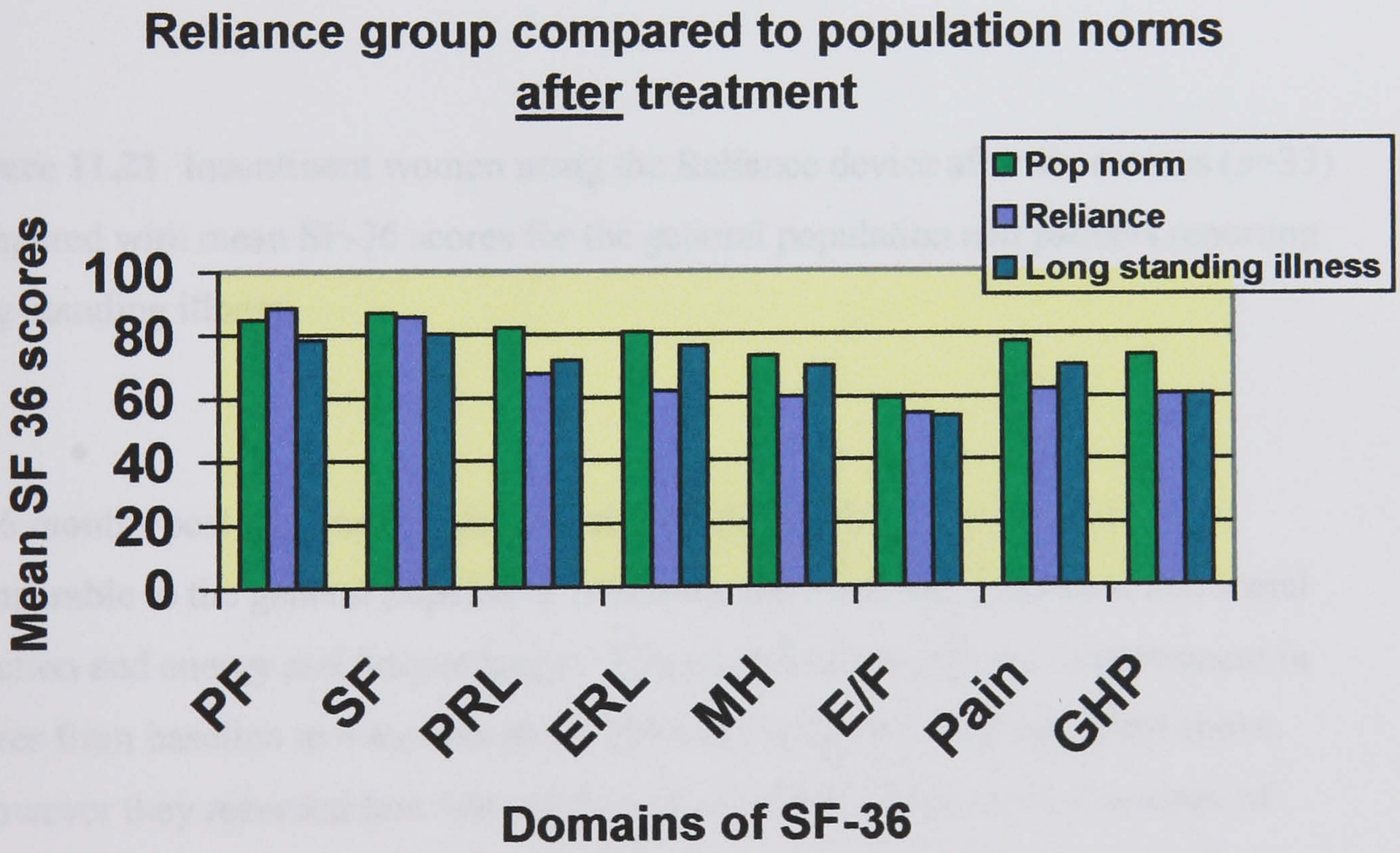


Figure 11.20 Data for incontinent women using the Reliance device after six months (n=33) compared with mean SF-36 scores for the general population and patients reporting long-standing illness.

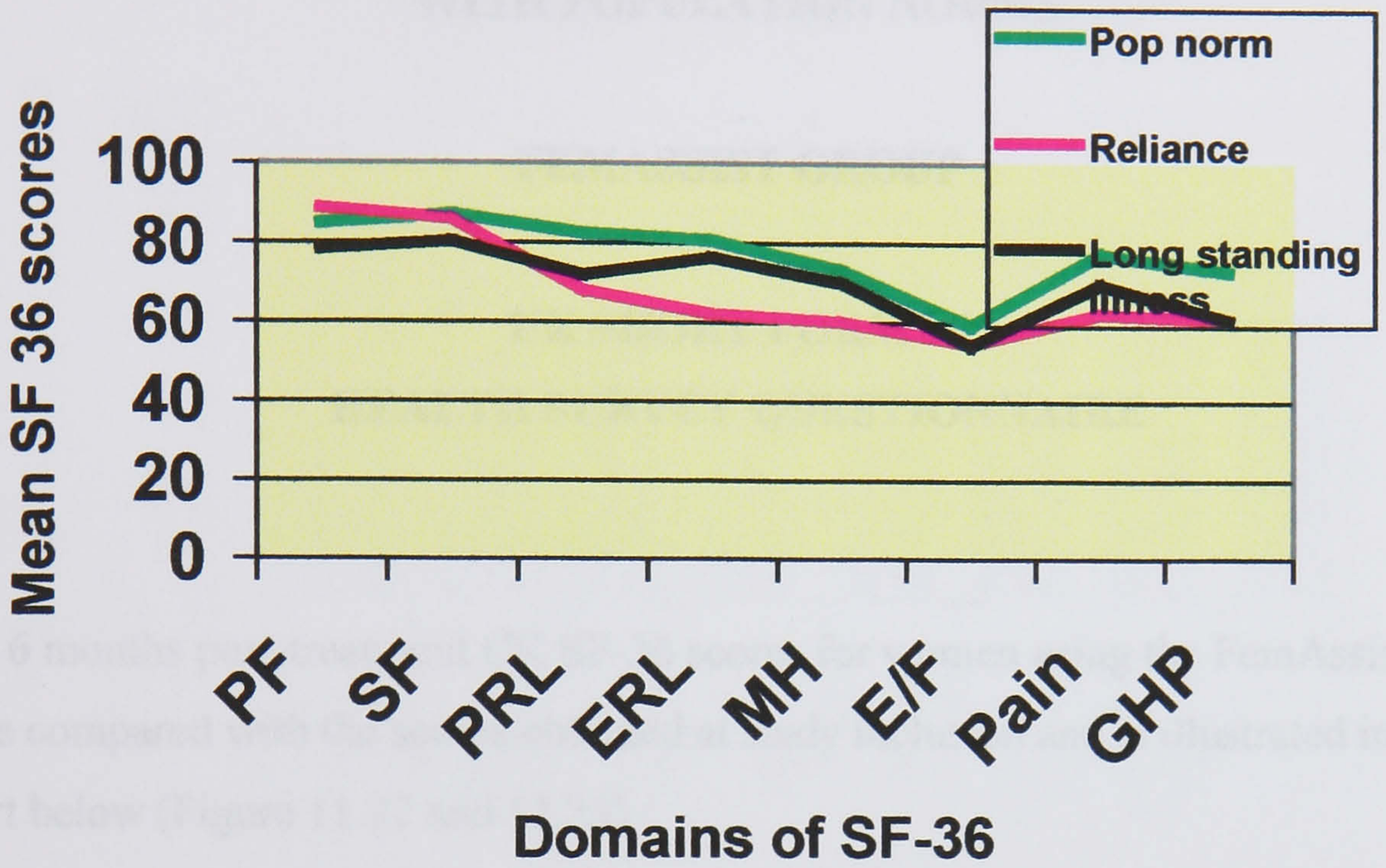


Figure 11.21 Incontinent women using the Reliance device after six months (n=33) compared with mean SF-36 scores for the general population and patients reporting long-standing illness.

By 6 months post-treatment with the Reliance device the study patients were comparable to the general population norms for the domains of physical and social function and energy and fatigue levels. This is consistent with the improvement in scores from baseline to 6 months post-treatment, which was demonstrated above. However they recorded less favourable quality of life scores in the measures of physical role limitation, emotional role limitation, mental health and pain. Their general perception of health was also less favourable and still comparable to patients with long-standing illness.

5B COMPARISON OF POST TREATMENT SCORES WITH POPULATION NORMS

FEMASSIST GROUP

UK SHORT FORM 36 HEALTH SURVEY QUESTIONNAIRE

The 6 months post-treatment UK SF-36 scores for women using the FemAssist device were compared with the scores obtained at study inclusion and is illustrated in the bar chart below (Figure 11.22 and 11.23)

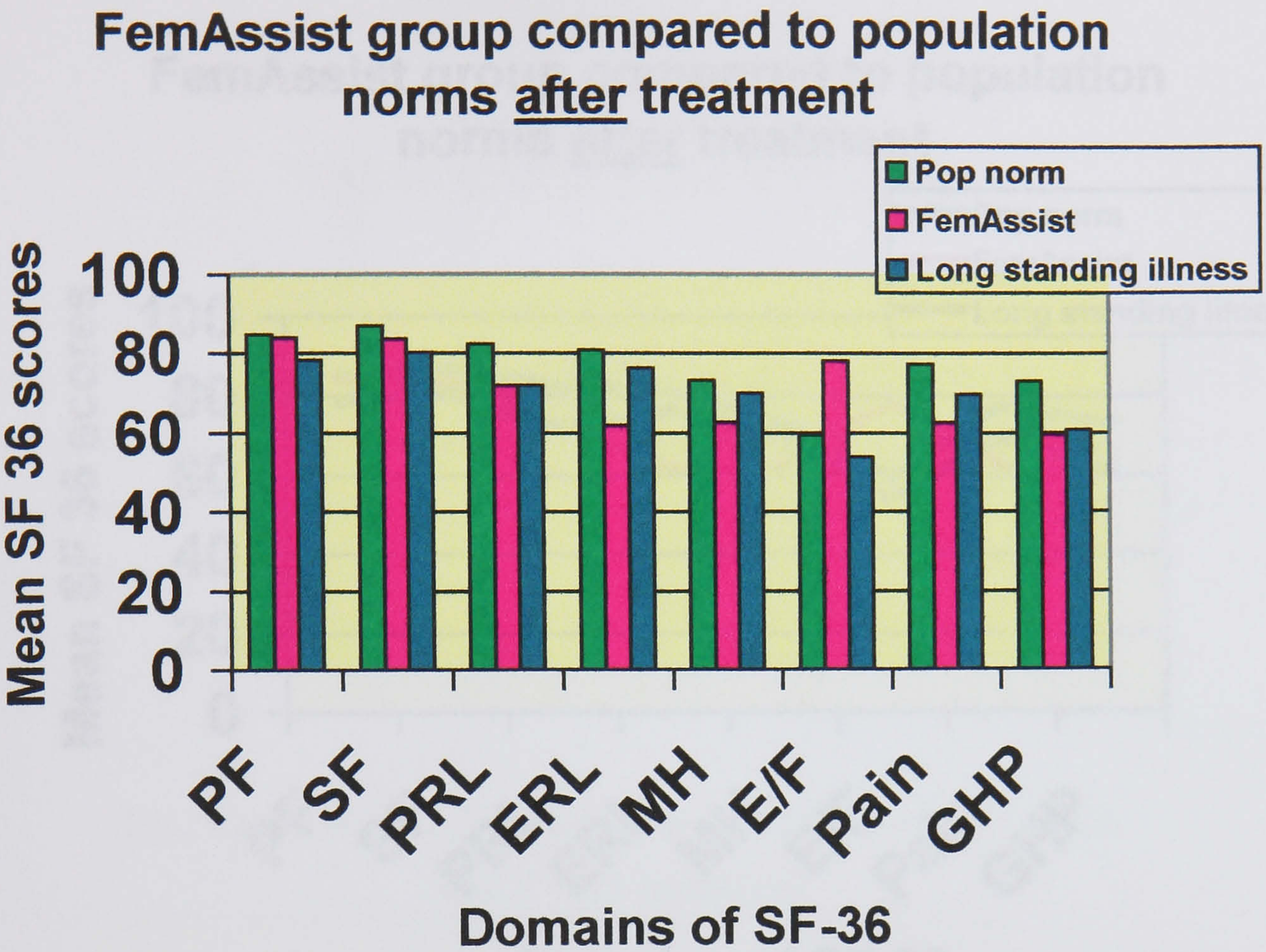


Figure 11.22 Data for incontinent women using the FemAssist device (n=36) after six months compared with mean SF-36 scores for the general population and patients reporting long standing illness.

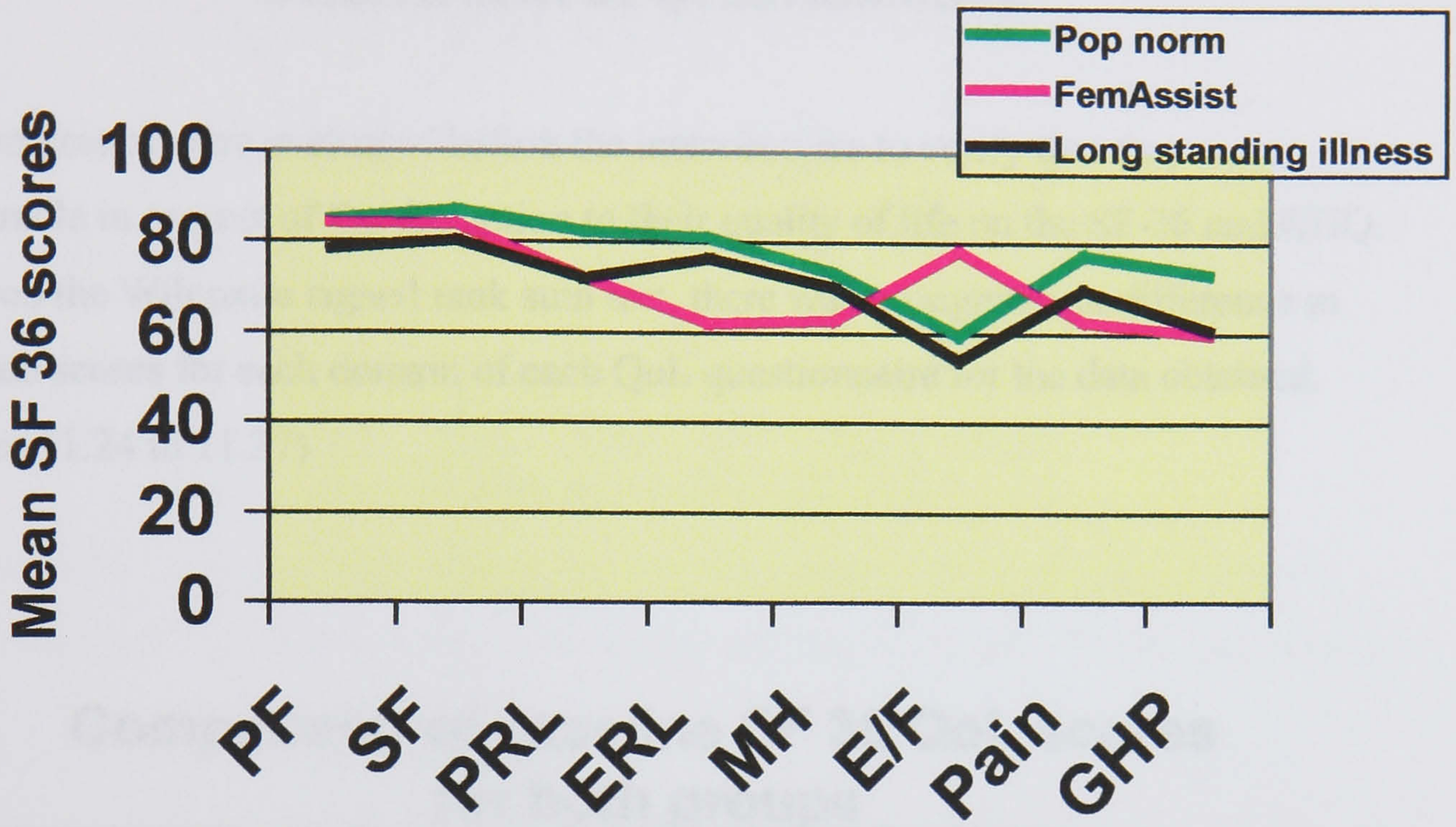


Figure 11.23 Data for incontinent women using the FemAssist device (n=36) after six months compared with mean SF-36 scores for the general population and patients reporting long standing illness.

GROUPS COMPARABLE AT BASELINE

UK SHORT FORM 36
HEALTH SURVEY QUESTIONNAIRE

The two groups were evaluated before the interventions to verify that they were comparable in respect of the disruption to their quality of life on the SF-36 and KHQ. Based on the Wilcoxon signed rank sum test, there was no significant difference in the mean scores for each domain of each QoL questionnaire for the data obtained. (Figures 11.24 to 11.27)

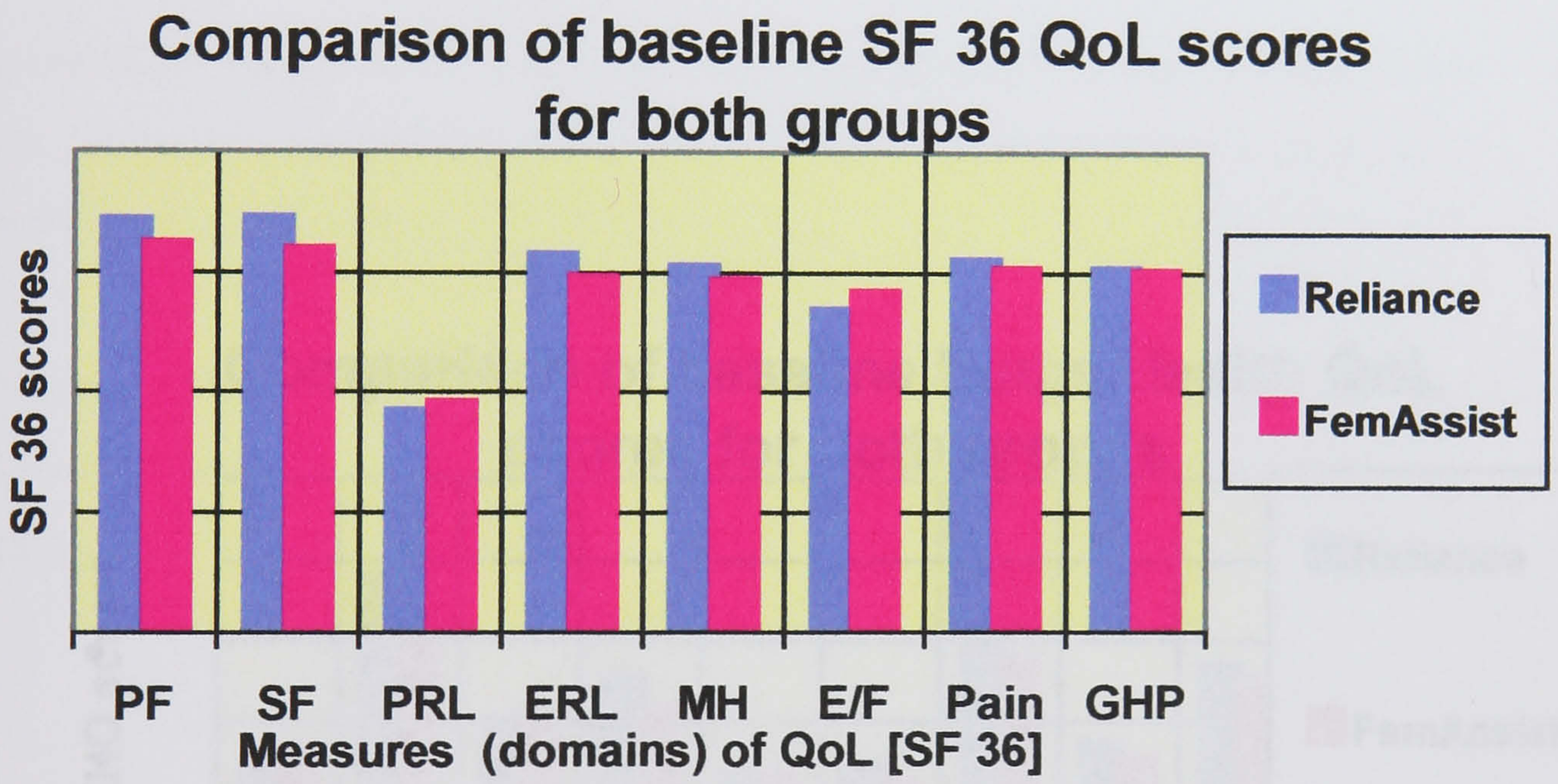


Figure 11.24 Bar chart illustrating that the two groups, FemAssist and Reliance users were well matched at entry to the study with respect to their SF 36 QoL scores.

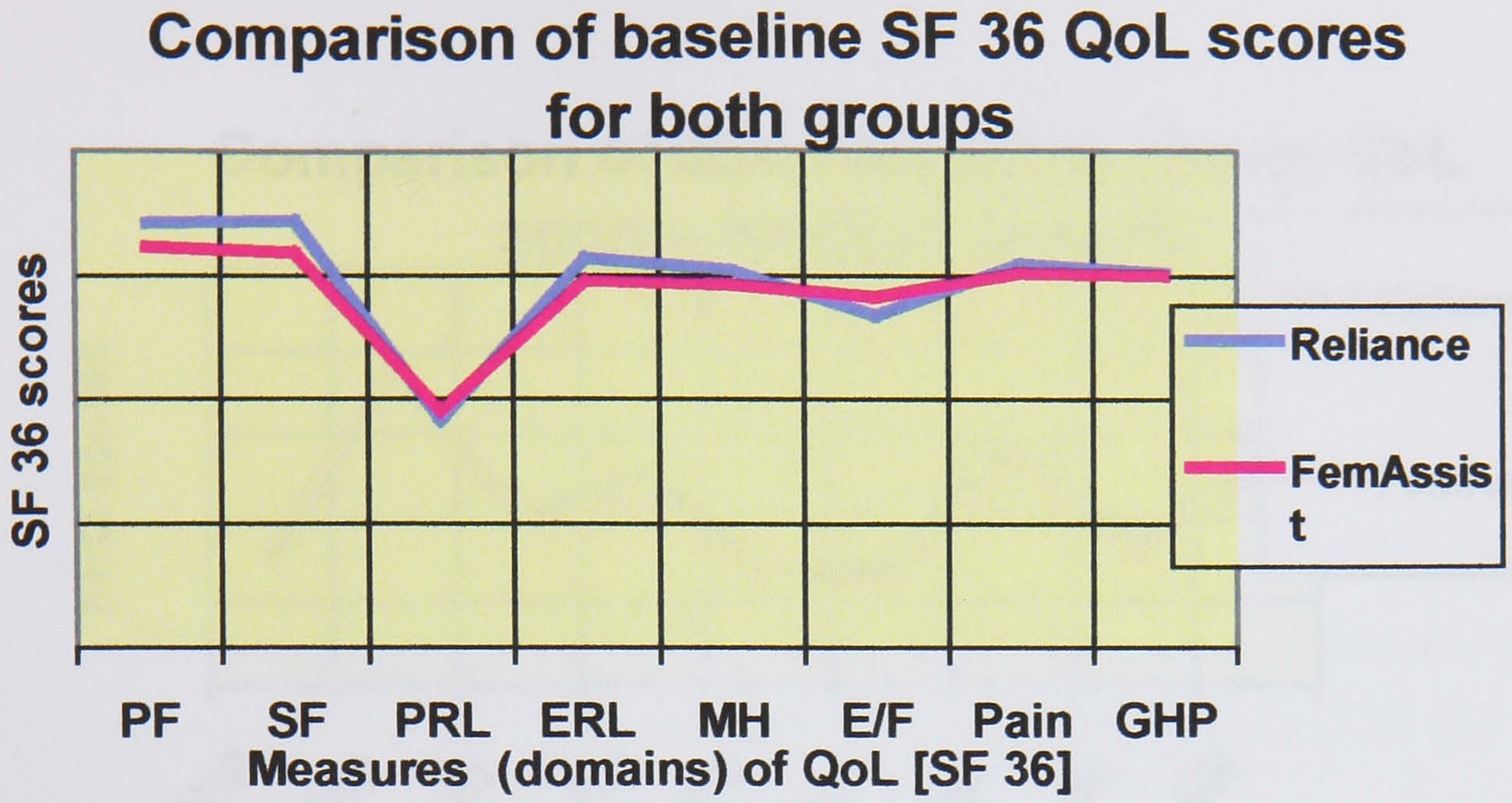


Figure 11.25 Line graph illustrating that the two groups, FemAssist and Reliance users, were well matched at entry to the study with respect to their SF 36 QoL scores.

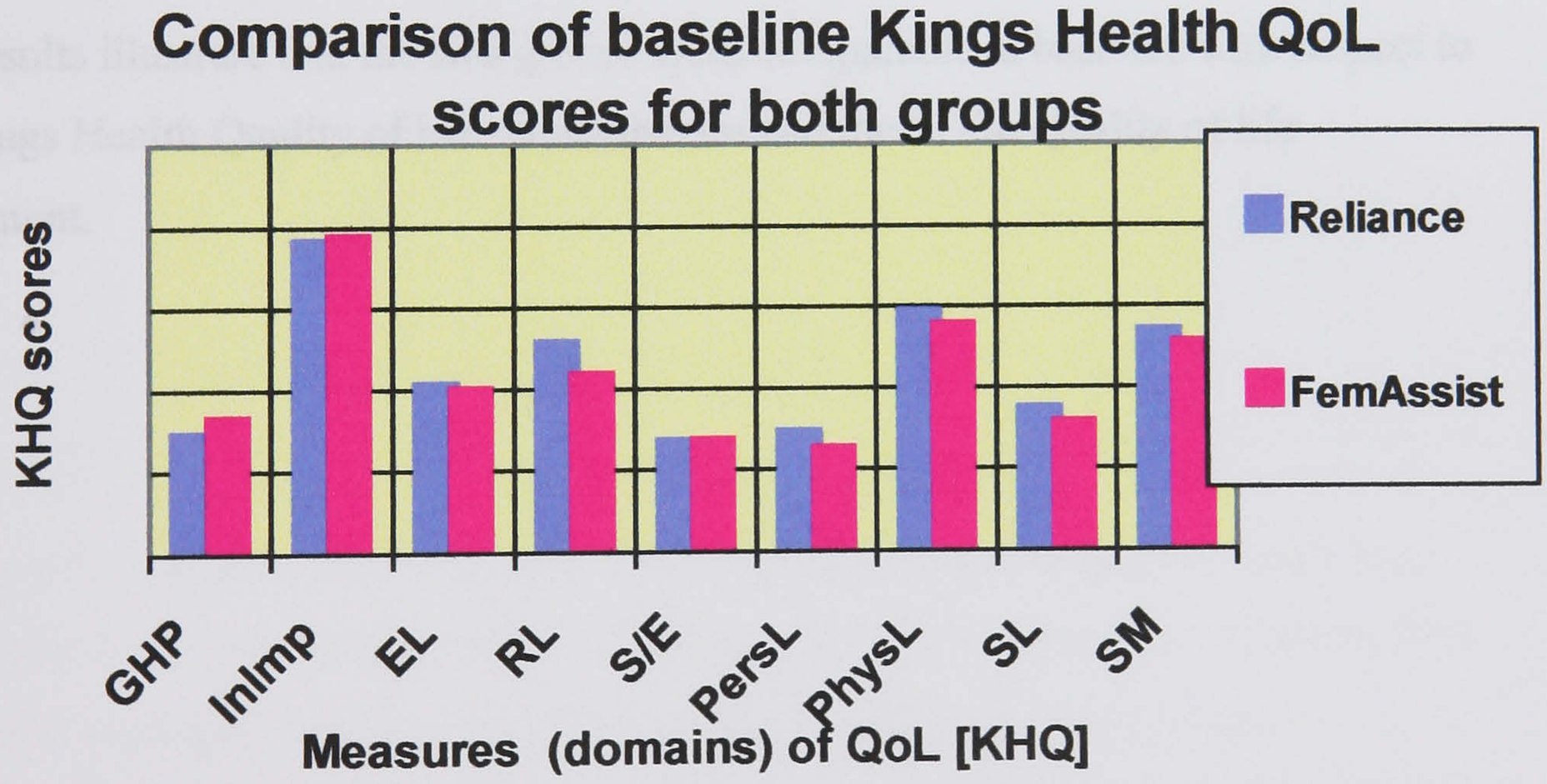


Figure 11.26 Bar chart illustrating that the two groups, FemAssist and Reliance users were well matched at entry to the study with respect to their Kings Health Questionnaire QoL scores.

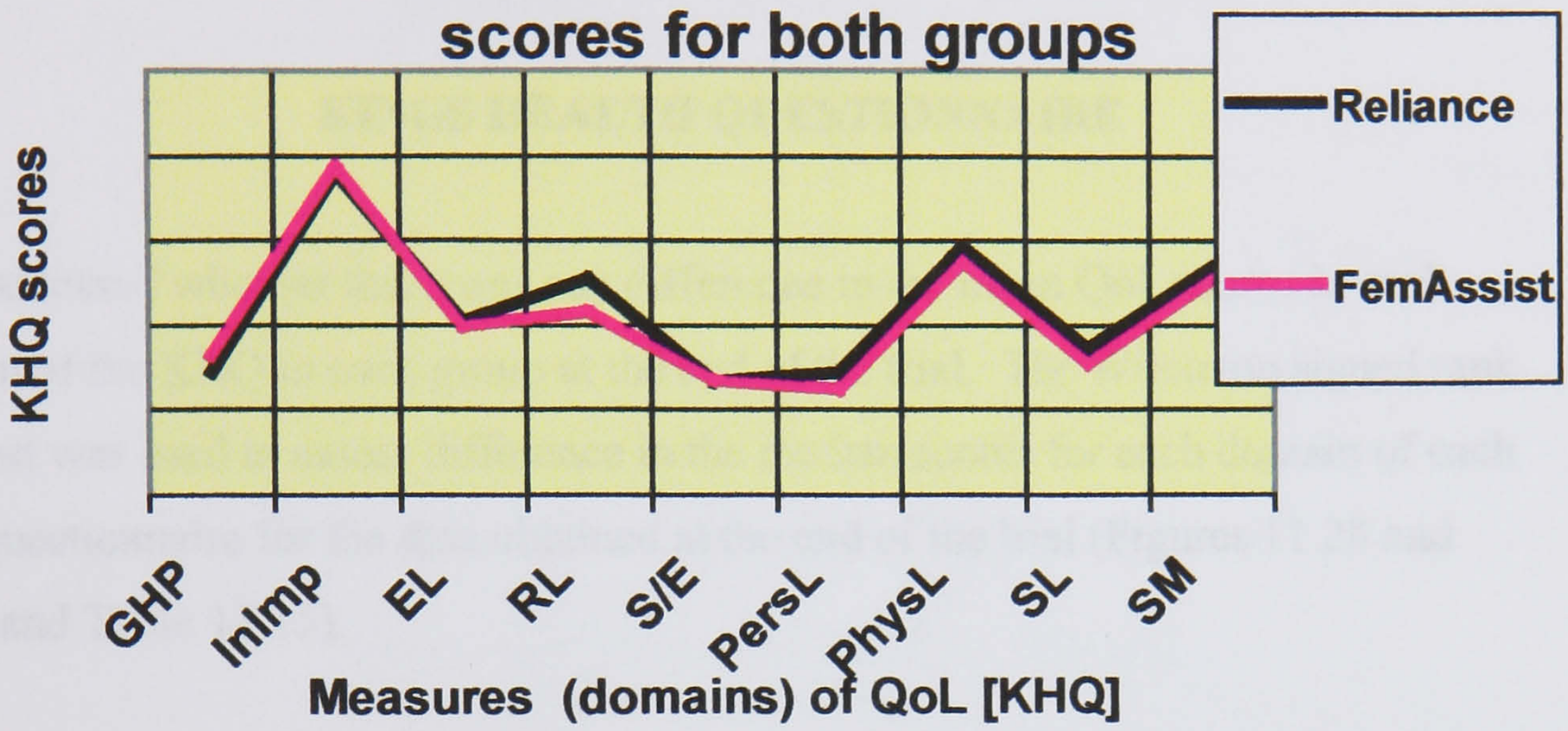


Figure 11.27 Line graph illustrating that the two groups, FemAssist and Reliance users, were well matched at entry to the study with respect to their Kings Health Questionnaire QoL scores.

The results illustrate that the two groups were comparable at baseline with respect to the Kings Health Quality of life questionnaire and the SF-36 Quality of life instrument.

COMPARISON OF POST TREATMENT QOL SCORES

FEMASSIST VS RELIANCE

KINGS HEALTH QUESTIONNAIRE

I also assessed whether there was any difference in the mean QoL scores in each domain of the KHQ in each group at the end of the trial. The Wilcoxon signed rank sum test was used to assess difference in the median scores for each domain of each QoL questionnaire for the data obtained at the end of the trial (Figures 11.28 and 11.29 and Table 11.15).

COMPARISON OF MEAN SCORES ON THE KINGS HEALTH QUESTIONNAIRE FOR BOTH GROUPS AFTER TREATMENT

Domain	GHP	InImp	EL	RL	S/E	PersL	PhysL	SL	SM
Reliance (n=31)	28.3	41.3	37.6	33.8	27.3	23.2	23.3	23.6	30.9
Femassist (n=36)	31.6	48.2	34.9	41.2	22.1	24.2	17.1	22.5	29.1
2-tail sig	0.635	**0.04**	0.845	**0.03**	**0.05**	0.781	**0.05**	0.355	0.645

Table 11.15 Summary of the estimates of the groups means and differences in the measures between the scores obtained using the KHQ 6-month post Reliance and FemAssist treatment. SD = standard deviation, SEM = standard error of mean, 95% CI = 95% confidence interval. {GHP = General health perception, InImp = Incontinence impact, EL = Emotional limitation, RL = Role limitation, S/E = Sleep/ energy disturbance, PersL = Personal limitation, PhysL= Physical limitation, SL = Social limitation, SM = Severity measures.}

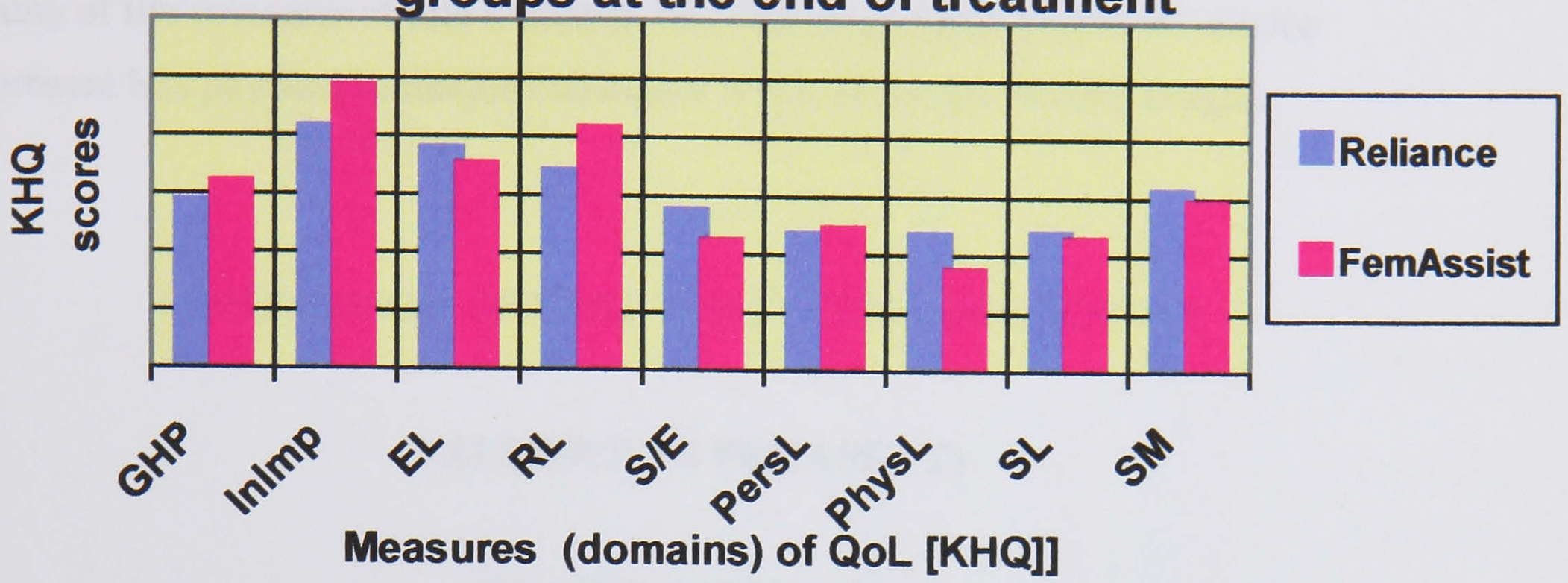


Figure 11.28 Bar chart demonstrating the differences in the Kings Health Questionnaire mean scores for the two groups as a result of using the different devices.

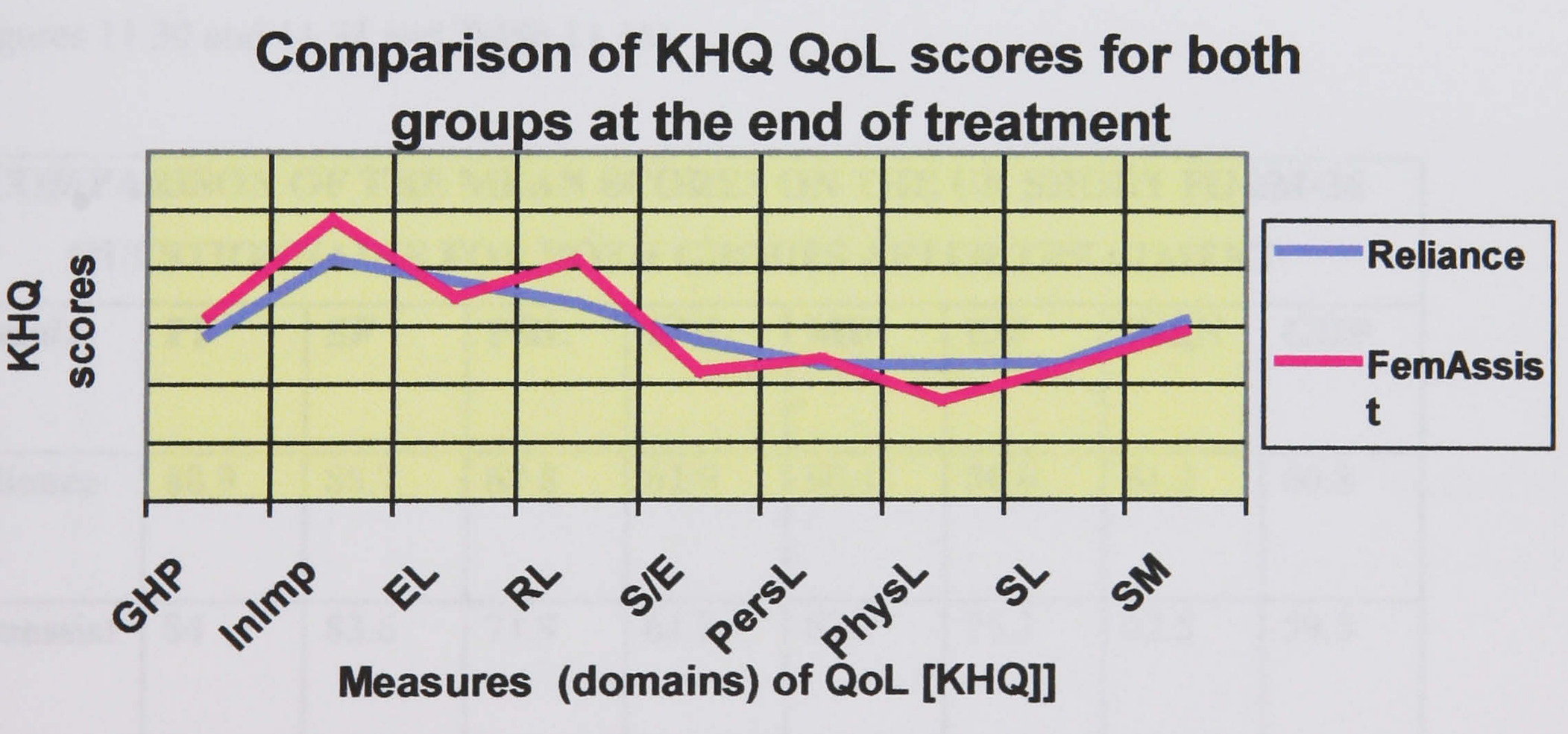


Figure 11.29 Line graph demonstrating the differences in the Kings Health Questionnaire mean scores for the two groups as a result of using the different devices.

The quality of life improvement in both groups as a consequence of device utilisation was very similar as assessed by the measures on the Kings Health Questionnaire. There was a significantly more favourable response in the Reliance group in the quality of life measures of role limitation but women using the FemAssist device expressed less physical limitation and higher levels of energy and less fatigue.

COMPARISON OF POST TREATMENT QOL SCORES

(RELIANCE VS FEMASSIST)

UK SHORT FORM 36
HEALTH SURVEY QUESTIONNAIRE

Assessment was also made of whether there was any difference in the mean QoL scores in each domain of the SF-36 questionnaire in each group at the end of the trial. The Wilcoxon signed rank sum test was used to assess difference in the median scores for each domain of each QoL questionnaire for the data obtained at the end of the trial (Figures 11.30 and 11.31 and Table 11.16).

COMPARISON OF THE MEAN SCORES ON THE UK SHORT FORM-36 QUESTIONNAIRE FOR BOTH GROUPS AFTER TREATMENT								
Domain	**PF**	**SF**	**PRL**	**ERL**	**MH**	**E/F**	**PAIN**	**GHP**
Reliance	88.9	85.7	67.8	61.9	60.1	54.6	61.2	60.8
Femassist	84	83.6	71.9	61.9	62.7	78.2	62.5	59.5
2-tail sig	**0.002**	0.22	**0.01**	0.945	0.067	**0.001**	0.876	0.416

Table 11.16 Summary and comparison of the mean SF-36 scores for women with GSI using the Reliance and FemAssist devices for 6 months. SD = standard deviation. [PF = physical function, SF = social function, PRL = physical role

limitation, ERL = emotional role limitation, MH = mental health, E/F = energy/fatigue, GHP = general health perception]

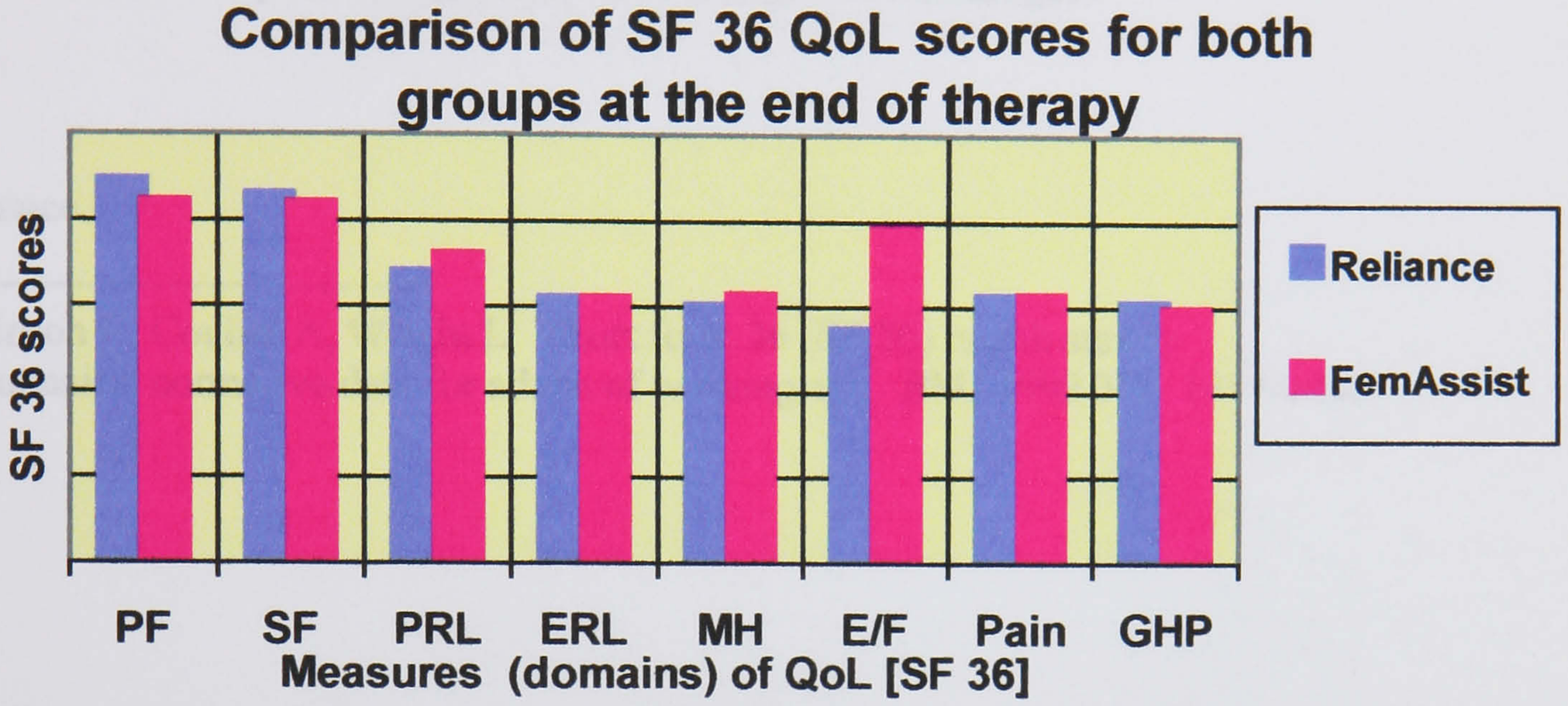


Figure 11.30 Bar chart demonstrating the differences in the SF 36 questionnaire scores for the two groups as a result of using the different devices.

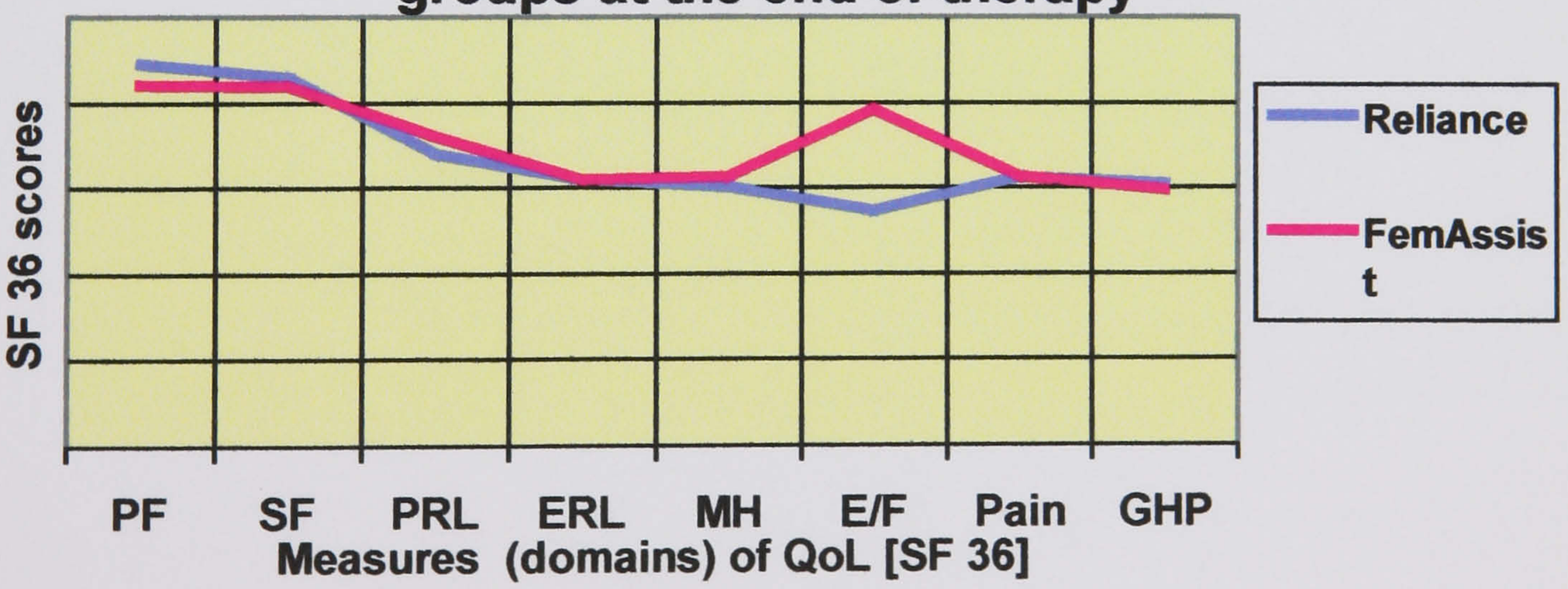


Figure 11.31 Line graph demonstrating the differences in the SF 36 questionnaire scores for the two groups as a result of using the different devices.

The quality of life improvement in both groups as a consequence of device utilisation was very similar as assessed by the measures on the SF-36 questionnaire. There was a marginally more favourable response in the Reliance group in the quality of life measures of physical function and physical role limitation but women using the FemAssist device expressed higher levels of energy and less fatigue.

Reference

---

[1] Jenkinson C, Coulter A, Wright L. Short form 36 (SF-36) health survey questionnaire: normative data for adults of working age. BMJ 1993 306: 1437-1440.

CHAPTER TWELVE

SIDE EFFECTS EXPERIENCED BY THE RELIANCE AND FEMASSIST GROUPS

The side effects, adverse events and complications experienced by both groups of women during device utilisation are summarised in tables 12.1 and 12.2. The adverse events of haematuria and pyuria are recorded and noted in the absence of bacteriuria and infection.

Adverse events and complications experienced during the trial in women using the *Reliance* device

	Number (%)			
	1 month	**3 months**	**6 months**	**Overall**
Spotting	4 (8.3%)	1 (2.1%)	0	5 (10.4%)
Urethritis/ inflammation	4 (8.3%)	0	0	4 (8.3%)
Haematuria	1 (2.1%)	0	0	1 (2.1%)
Pyuria	1 (2.1%)	0	0	1 (2.1%)
Asymptomatic Bacteriuria	2 (4.2%)	1 (2.1%)	2 (4.2%)	5 (10.4%)
UTI	2 (4.2%)	0	3 (6.3%)	5 (10.4%)

Table 12.1 Side effects, adverse events and complications associated with Reliance device use.

Adverse events and complications experienced during the trial in women using the *FemAssist* device				
	Number (%)			
	1 month	3 months	6 months	Overall
Spotting	6 (11.3%)	3 (5.7%)	4 (7.5%)	13 (24.5%)
Urethritis/ Inflammation	1(1.9%)	1 (1.9%)	0	2 (3.8%)
Haematuria	0	0	0	0
Pyuria	0	0	0	0
Asymptomatic Bacteriuria	3 (5.7%)	2 (3.8%)	2 (3.8%)	7 (13.2%)
UTI	2 (3.8%)	1 (1.9%)	3 (5.7%)	6 (11.3%)

Table 12.2 Side effects, adverse events and complications associated with FemAssist device use.

There were no serious adverse events reported in either group.

Device migration

There was no case of device migration into the urethra or bladder with use of either device. However, on one occasion when a subject was being instructed on how to use and insert the Reliance device, it was noted that she inserted it into the urethra with the meatal plate of the device just beyond the meatus. With a lubricated gloved finger, the device was milked back by external pressure on the urethra. There were no cases of obvious urethral trauma externally on clinical examination.

Spotting

Spotting was much more commonly reported in women using the FemAssist device and was probably related to the suction effect of the device. It occurred with aggressive overuse of the device and not with less frequent utilisation. All incidences resolved after a short period of approximately 24 hours of suspended use of the device.

Urethritis

Urethritis was much more common in the Reliance group and was expected of a device inserted into the urethra, although overall, the number of cases was only few. It was nevertheless a cause for patients to withdraw from the trial.

Haematuria

Haematuria was not observed on routine testing in the absence of infection in the FemAssist group and only rarely in the Reliance group. It is likely that this occurred much more frequently in clinical practice and would be recorded more often with increased frequency of urinalysis.

Bacteriuria

Cases of asymptomatic bacteriuria were similar in both groups of device users and were one of the most frequently noted adverse events in the study. Both symptomatic and asymptomatic bacteriuria were treated with the appropriate antimicrobial therapy for 5 days while device use was suspended.

URINARY TRACT INFECTION

Reliance group

There were five (10.4%) symptomatic infections per 188 patient months of use which corresponds to one UTI per 37.6 patient months. No patient experienced fever, chills,

and loin or flank pain. None of the subjects suffered any sequelae of their positive urine cultures.

FemAssist group

There were six (11.3%) symptomatic infections per 237 patient months of use, which corresponds to one UTI per 39.5 patient months. No patient experienced fever, chills, loin or flank pain and none of the subjects suffered any sequelae of their positive urine cultures.

MEATAL / VAGINAL CHANGES IN DEVICE USERS

Erythema

A small area of erythema was noted in all patients using the FemAssist device, which was discrete, flush to the skin and under the area of contact with the device. The erythema was noted once the device was removed and resolved after 5 – 10 min. In no case was erythema persistent. This finding was consistent with the pressure effect of the device. No sequelae were reported. Erythema was noted in two women using the Reliance device. The area of skin change was adjacent to the meatal plate of the device on the inner aspect of the labia minora. The two women discontinued the trial as a result.

Petechial Haemorrhage

Small mild petechial haemorrhages were noted in 8 (15.1%) women overall using the FemAssist device, adjacent to the external urethral meatus, under the points of contact with the device. These were consistent with the trauma associated with the vacuum effect of the device. No subject developed bruising which could be described as ecchymosis as has been described with other devices such as the Cap Sure. Petechial haemorrhages were not noted in Reliance device users.

There were no documented cases of urethral prolapse, vaginal bleeding, urinary retention or gross haematuria or frank mucosal bleeding during the study.

COMFORT

The sensation of discomfort or irritation did not appear to signify any physical tissue damage to the vagina and urethral meatus when physical examination was performed except in one case. One subject felt labial irritation and discomfort from the edges of the FemAssist device. It was felt that the rim of the device was in contact with the medial walls of the labia majora. The injury was compounded by the patient's clinical findings of mild atrophic vaginitis and a tight dry vaginal introitus. Device use was discontinued for one week while the subject applied oestrogen cream locally to the vagina (Ovestin cream – one application daily). The duration of treatment was one week. The subject was keen to restart device usage so this was resumed without adverse events for the rest of the trial. She was however, encouraged to use Vaseline ointment to the skin of the vagina in addition to lubricating the contact surface of the device to correct for skin dryness and susceptibility to trauma. The patient's age was 77 years.

CHAPTER THIRTEEN

ANALYSIS OF DROPOUTS

NON-RESPONDERS

Planning and organisation was geared to obtaining the highest possible recruitment but some "non-responders" remained. Non-responders are unlikely to be typical of the remainder of the sample. They may be more or less likely to suffer GSI and hence their omission is likely to lead to biases when drawing conclusions from the results of the sample. As much indirect data as possible was obtained about the non-responders so as to make an estimate of the kind of bias which may be introduced by their omission.

The number of subjects who dropped out of the study and the reasons given for discontinuing the trial are shown in tables.

Number of subjects dropping out of the trial				
	1 month	**3 months**	**6 months**	**overall**
Reliance	6 (12.5%)	7 (14.6%)	2 (4.2%)	17 (35.4%)
FemAssist	6 (11.3%)	6 (11.3%)	5 (9.4%)	17 (32.1%)

Table 13.1 Number of women who elected to discontinue the trial at each period of assessment and overall for each device group.

Reasons for discontinuing the trial				
	Lost to follow-up	**Inhibition**	**Urethritis**	**Poor efficacy**
Reliance (n=17)	8	3	4	2
FemAssist (n=17)	10	0	1	6

Table 13.2 Reasons given by the subjects in each group for discontinuing the trial.

For each group of device users, the demographic, historical and clinical parameters were examined between the set of women who completed the study and those who did not (Table 13.3 and 13.4). This was performed to ascertain if there were any

statistically significant differences observed between women who completed the study and those who did not when patient background characteristics were examined.

Differences observed between women who completed the study and those who did not (Reliance group)			
Background characteristics	**Not completing 6 months (n=17)**	**Completed study (n=31)**	**Paired difference p-value**
Mean age (years)	46.9	52.24	0.143
Mean number of IEPD	4.67	5.15	0.22
Mean number of incontinence pads used per 5 days	11.25	10.55	0.67
Mean PWT gain at baseline (g/hr)	28.7	33	0.35

Table 13.3 The differences in demographic and clinical parameters for Reliance device users between the set of women who completed the study and those who did not.

Despite discontinuing treatment (n=17), 7 (41.2%) women felt that it had been beneficial in stopping leakage whilst they were able to use a Reliance device and four (23.5%) found benefit with the FemAssist device.

All "responders" in both groups felt that their lives were still affected to some degree by their urinary symptoms and this was reflected in the QoL questionnaires. No subject felt that their treatment had been worse than their urinary symptoms.

There was no difference in the mean age, menopausal status or the use of HRT between those completing and not completing the study in either device group. Nor was there any difference detected between the groups in the severity of GSI detected on urodynamic testing.

Differences observed between women who completed the study and those who did not (FemAssist group)			
Background characteristics	**Not completing 6 months (n=17)**	**Completed study (n=36)**	**Paired difference p-value**
Mean age (years)	47.5	50.1	0.133
Mean number of IEPD	4.88	5.10	0.42
Mean number of incontinence pads used per 5 days	10.2	11.3	0.12
Mean PWT gain at baseline (g/hr)	30.1	28.9	0.48

Table 13.4 The differences in demographic and clinical parameters for FemAssist device users between the set of women who completed the study and those who did not.

The majority of women who discontinued the trial had a greater degree of "bothersome" foreign body sensation and discomfort with each device used. They also experienced a greater degree of difficulty with device placement than "responders".

Urine loss with specific activities and the overall degree of control of "wetness" was similar in responders and non-responders using the Reliance device. However, these two outcome measures were less favourable in those discontinuing use of the FemAssist device.

Those who discontinued the trial had significantly worse outcome in the measures of urinary leakage assessed on the urinary diary and PWT data in both groups at one month.

QUALITY OF LIFE

Reliance

Women who discontinued using the Reliance device had significantly less favourable scores (KHQ) in the domains of "incontinence impact" (p=0.05), severity of symptoms (p=0.02) and "physical role limitation" (p=0.02) than women who completed the trial of the Reliance device. There were no significant differences in the other domains assessed by the KHQ.

The only difference detected between responders and non-responders in the scores of the SF36 was in the domain of "role limitation due to physical problems". Non-responders had significantly less favourable scores in this domain.

FemAssist

Women who discontinued using the FemAssist device had significantly less favourable scores (KHQ) in the domains of "Incontinence impact" (p = 0.01) and "severity of symptoms" (p = 0.04)

No difference was detected between responders and non-responders in the domains of the SF36.

CHAPTER FOURTEEN

CONCLUSION AND FUTURE RESEARCH

The purpose of evaluation is to demonstrate whether these continence devices have been successful or to what degree they have failed to achieve the stated aims. In this study it was possible to determine not only whether the devices were effective at achieving the desired outcome but with what consequences. This been clarified, one can then relate this narrow perspective to an overall framework which incorporates the use of continence devices within a coherent health strategy for addressing the needs of the incontinent woman. Based on the activities upon which they were tested, the women recruited to the trial had a major degree of "wetness" or severity of incontinence. The two groups were also comparable in respect of features known to affect outcome. Additionally, one of the merits of this study is that responders to treatment were defined clinically and with an established scale score and hence has the advantage of certainty about the exact degree of response.

PATIENT SATISFACTION

No matter how well a device works, if it is uncomfortable or difficult to use, its role in treating incontinence is limited. Over time, there is a trend for both devices to become more comfortable to wear and easier to place. The FemAssist device is especially consistently rated better than the Reliance in this regard. Proficiency at correct placement is the key to this phenomenon. The sensation of discomfort or irritation did not appear to signify any physical tissue damage to the vagina and urethral meatus.

Women experience similar foreign body sensation when using either device with a reduction in foreign body sensation over time. This sensation occurs early in device utilisation or not at all, with no residual effect. Overall, there is a high user satisfaction with the FemAssist device. Experienced gained with continued use (learning curve) proves beneficial in terms of ease of insertion and placement, comfort of use and habituation for both devices. The experience seems to be more amenable with the FemAssist than the Reliance device.

PATIENT RATED DRYNESS

Both the FemAssist and Reliance devices allow most users to feel completely dry or significant improvement while performing specific activities and in an overall

manner. As a result, women are also likely to participation in more provocative manoeuvres over time. However, Reliance users score consistently higher than those using the FemAssist. Incontinent women do not feel they are made worse by device use.

QUANTIFICATION OF URINE LOSS

Incontinence episodes per day

Use of either device is associated with a significant reduction in the mean number of incontinence episodes per day. The individual patient responses categorise most women to be made "moderately or significantly improved" in the Reliance group. No subject is made "dry" or "worse" with device use in this group. These responses are consistently maintained over time.

The individual patient responses categorise most women to be made "slightly, moderately or significantly improved" in the FemAssist group. The FemAssist device is more likely to result in better reduction in the mean IEPD with longer duration of use. No subject using this device is made "worse" but approximately 11% are categorised as "dry". These responses are also consistently maintained over time. Comparison with other studies is illustrated in table 14.1.

Incontinence episodes with device use (mean)		
Device Type	**Baseline**	**Study conclusion**
Adhesive continence patch [1]	13.3/week	4.3/week
CapSure shield [2].	3.4/day	0.6/day
Introl [3]	4/day	0.4/day
FemAssist (present study)	**4.9/day**	**1/day**
Reliance (present study)	**5.11/day**	**1.33/day**

Table 14.1 Studies of different devices recording mean incontinence episodes with device utilisation.

Number of continence pads used over 5-days

Use of either device is associated with a significant reduction in the mean number of continence pads used over 5 days. The individual patient responses categorise most women to be made "significantly improved" in the Reliance group at an early assessment. No subject is made "dry" or "worse" with device use in this group. These responses are consistently maintained over time.

The individual patient responses categorise most women to be made "no better" with initial use of the FemAssist device. With continued use they are made "significantly improved" over time but not categorised as "dry". Few studies have used the number of continence pads utilised as an outcome measure. The Conveen continence guard is associated with a reduction in pads used per day from a baseline of 2.5 to 1.6 at study conclusion [4]. The FemAssist and Reliance compare favourably with these figures (11.1 pads to 4.33 per 5 days [FemAssist], and 10.6 pads to 3.43 pads per 5 days [Reliance].

Pad weight test data

The effectiveness or control of incontinence as determined by pad weight testing in both groups is associated with a significant reduction in urine loss during device use. The individual patient responses rate most women to be "dry" using the Reliance device. The remainder is improved to some degree.

The individual patient responses characterise most women to be "moderately improved" or "slightly improved" using the FemAssist device. The remainder is "significantly improved" or "unchanged". Only a few could be categorised as "dry". Comparison with other studies is illustrated in table 14.2.

Mean pad weight test gains for various continence devices		
Device Type	**Baseline**	**Study conclusion**
Adhesive continence patch [1]	1.1g/hr	0.44g/hr
CapSure shield [2]	6.8g/hr	0.18g/hr
Conveen (Hahn et al 1996) [5]	41.6g/hr	13.9g/hr
Introl (Foote et al 1996) [3]	57g/hr	9g/hr
FemAssist (Prashar et al)[6].	55.7g/hr	17.8g/hr
FemAssist (Tincello et al 1997)[7].	21g/hr	4.9g/hr
FemAssist (present study)	**28.3g/hr**	**3.6g/hr**
Reliance (Staskin et al 1996) [8]	42.7g/hr	2.2g/hr
Reliance (Pigne et al 1997)[9].	36g/hr	10g/hr
Reliance (Miller et al 1996)[10].	46.4g/hr	2.4g/hr
Reliance (present study)	**31.2g/hr**	**1.3g/hr**

Table 14.2 Studies of different devices recording mean PWT gains with device utilisation.

FEMASSIST VS RELIANCE

The Reliance device is far superior to the FemAssist in reducing the amount of urine lost on a pad-weighing test and is more likely to render a patient "dry". However this supremacy is not extended to other measures to quantify leakage of urine. The number of incontinence episodes per day and the number of continence pads needed over five days at the study end-point are comparable in each group of device users. It is tempting to interpret that what we are seeing at a given time in the relatively artificial setting of the laboratory is an accurate reflection of what a woman experiences during her daily activities while using a continence device. Nevertheless, these last two measures are much more in keeping with patient experiences and expectations and hence must be bestowed greater accord. The overall impression was that the urinary diary data better reflected the patients sentiment while wearing the devices from day to day rather than the PWT results.

Altogether, control of stress incontinence is not complete in the majority of women using either device, but particularly so in the case of the FemAssist group. This is

largely due to the limitations of this device, not having sufficient adhesive power to consistently prevent urinary leakage around the vacuum seal. However, for a significant proportion of women it is, like the Reliance device, effective for severe and moderate genuine stress incontinence alike.

RISK REDUCTION AND NUMBERS NEEDED TO BE TREATED.

The relative risk reduction, the absolute risk reduction and numbers needed to be treated demonstrate a high degree of device efficacy in both groups. To achieve a result of better than 2 or more incontinence episodes/day 1.1 incontinent women would need to be treated using either device. To achieve a result of better than 3 or more pads used per 5 days, 1.4 incontinent women would need to be treated using a Reliance device and 1.6 with a FemAssist device.

Similarly, to achieve a result of better than 3g or less mean PWT gain, 2.1 incontinent women would need to be treated using a Reliance device and 3.8 with a FemAssist device.

The number needed to be treated is time-dependent, which may affect the relative rankings of the numbers needed to be treated in trials of different lengths. Only if a treatment produces a constant relative risk reduction over time does the number needed to be treated decrease as the length of follow up increase.

There is another disadvantage to combining the baseline risk and risk reduction into a single number in determining the absolute risk reduction and number needed to be treated. It simply reflects the average number of patients that must be treated in order to prevent some degree of incontinence, but does not indicate the fate of the other patients. At our present level of knowledge we have clues but can not precisely predict which one of the patients will be responsive to therapy with a continence device and in whom the therapy will have side effects.

TIME OF BENEFIT

An important finding in this study is that both devices maintain efficacy for a period of six months after response to initial treatment. One addendum is that for most women, they must use the FemAssist device for at least one month before the greatest benefit can be expected. The advantage of the Reliance is consolidated by the shorter

time to experience an optimal response. Nevertheless, efficacy consistency at the end-point of the study suggests that this would also be maintained in the long term for both devices.

MECHANISM OF ACTION AND RESIDUAL EFFECT

The Reliance appears to work immediately. It is a relatively inflexible device and it is our clinical impression that when in place, there is diminished mobility of the urethra and bladder neck when patients strain. In addition to the device being obstructive to the outflow of urine, it may also help to maintain proper pressure transmission to the proximal urethra. The balloon tip permits the device to remain in place during normal and strenuous exercise.

When using the FemAssist, some women require a longer period of time before mastering correct device placement so as to gain an optimal effect. It is purely an observation, but the FemAssist appears to have a residual effect whereby some women experienced persistence of improvement after device discontinuation and may provide a potential therapeutic effect. This may have occurred because of the indirect biofeedback effect or bladder training behavioural exercise of keeping a urinary diary or because of being closely involved in a clinical trial. Alternatively, there may be an independent resolute effect possibly due to a physical consequence. One can only speculate that this is due to the aftermath on the soft tissue microenvironment in the region of the periurethral vasculature causing increased blood flow, oedema and congestion of the tissues around the bladder neck and proximal urethra. This plexus is known to be a contributing factor in the mechanism of urinary continence in women. One theory explains GSI on the basis of short urethral length [11]. Intra-operative studies have shown that stretching of the urethral smooth muscle sphincter mechanism results in significant increase in urethral functional length and closure pressure [12]. It may be that the presence of the FemAssist device over the external meatus and the suction action it applies causes stretch of these critical structures and coaptation of the walls of the urethra. This will have the effect of increasing urethral resistance to escape of urine at rest, during bladder filling and under conditions of stress, and changes in position. This clinical observation requires further study

QUALITY OF LIFE

It is possible to assess the quality of life of women with urinary incontinence using multi-dimensional quality of life questionnaires such as the SF-36 and the KHQ combined. Although clinical trials often report significant improvement in urinary symptoms and objective pad test results following device use, these may be of limited clinical value if the women themselves do not experience improved QoL. Quality of life assessment is of clinical relevance as the scales can quantify the impact of urinary incontinence and the scores can show an improvement following successful treatment. For this reason QoL assessment would appear to be an important inclusion in clinical trials of these new devices for stress incontinence.

BASELINE QUALITY OF LIFE SCORES

The baseline Kings Health Questionnaire (and SF-36) quality of life scores for women randomised to use both device portray the majority of incontinent women as a group who consider their general health to be good. As might be expected with a disease specific questionnaire, incontinence impact scores are higher than those of all other domains. Physical and role limitation and severity measures are moderately influenced by GSI. Sleep and energy least affect the incontinent women but personal and social limitation are slightly more altered while emotional limitation is moderately higher in comparison.

The SF-36 questionnaire also demonstrates that incontinent women suffered mostly in the domains of physical role limitation with moderate but certain disruption to their quality of life in other domains.

QUALITY OF LIFE SCORES AFTER TREATMENT

KINGS HEALTH QUESTIONNAIRE

RELIANCE GROUP

Because incontinence affects interpersonal aspects of life most dramatically, it is gratifying that following treatment with the Reliance, device women with GSI experience an improvement in their quality of life with the least constraint in the

domains of personal and social limitation and energy, while the domains of incontinence impact, although influenced in a favourable direction, still cause the most interference. The greatest changes in better quality of life are observed in the domains of incontinence impact, severity measures, physical social and role limitation. These alterations are obvious to the patients and considered clinically evident. Overall, Reliance device users do not adjust their general health perception and energy levels. They are still limited by emotions and personal feelings although not as greatly.

FEMASSIST GROUP

Following utilisation of the FemAssist device the quality of life (KHQ and SF-36) domains of personal and social limitation and energy are least disrupted while the other domains are not as well improved. Greatest changes in the quality of life of women with GSI using the FemAssist device are observed in the domains of incontinence impact, energy levels, physical and social limitation and severity measures of incontinence. These modifications are remarkable and also considered clinically significant. However, the domain of incontinence impact still causes the most problem for incontinent women using the FemAssist device similar to the findings in women using the Reliance. There is not much alteration in their general health perception, emotional, role and personal limitation however.

SF-36 QUESTIONNAIRE

The greatest changes in the SF-36 scores were observed in the domains of physical and social function and physical role limitation and were similar in both groups.

BASELINE DATA COMPARED WITH POPULATION NORMS AND PATIENTS WITH LONG STANDING ILLNESS

At study inclusion, both groups of incontinent women had poorer quality of life in all the domains of the UK SF-36 quality of life questionnaire than that which is expected for healthy women in the general population. In particular they had a less favourable perception of their general health – albeit still good.

The incontinent women in this study are similar to those with long-standing illness in the domains of general health perception, energy and fatigue levels. Pain does not feature to be a problem as in other chronic illnesses, although social function and emotional role limitations are greater for women with urinary incontinence.

COMPARISON OF POST TREATMENT SCORES WITH POPULATION NORMS

After treatment with both the Reliance and FemAssist devices, the QoL domains (UK SF-36) of physical and social function and energy and fatigue levels are similar to healthy women in the general population. However they do not enjoy the same favourable quality of life scores in the measures of physical role limitation, emotional role limitation, mental health and pain.

COMPARISON OF POST TREATMENT QOL SCORES FEMASSIST VS RELIANCE

At the end of the study women using the Reliance and FemAssist devices express a similar perception of their general health and their emotional personal and social limitations. Significant differences could be detected between the devices as to the impact of incontinence on their lives (KHQ). Significantly better QoL scores are obtained in the domains of incontinence impact and role limitation in Reliance users whereas FemAssist users score better in the domains of sleep/energy disturbance and physical limitation. Interestingly, there is no real difference in the measures of severity of incontinence between the groups, with both devices providing a favourable response in this domain.

There are significant differences in the SF-36 scores detected after device use with more favourable QoL conferred by the FemAssist device in the domains of sleep/energy and physical role limitation. Reliance device users are accorded better QoL in the domains of physical function. Device usage does not result in any significant difference between the groups in the domains of general health perception, pain, mental health, emotional role limitation and social function.

RESPONDERS Vs NON-RESPONDERS

The study has demonstrated that urinary incontinence results in impairment in many aspects of the quality of life of sufferers, yet it is not possible to predict on the basis of urinary symptoms and the severity of incontinence alone the degree of this impairment. All told, the improvement seen in QoL scores is determined by the initial severity of the QoL score, the sensitivity of the questionnaire to change and the degree of improvement offered by the particular device.
Age, menopause status or the use of HRT are not modifying factors, but younger women appeared to have greater overall impairment in their quality of life than older women. Nevertheless, this research shows that elderly women with GSI have significant QoL impairment as a result of their urinary symptoms and are equally likely to benefit from the use of a continence device as younger women.

If women have significant bothersome foreign body sensation, discomfort or difficulty with placement of a device, they are much more likely to discontinue device use even though the device may be beneficial in reducing the severity of incontinence. This really characterises the experience of the Reliance user, whereby non-responders enjoyed initial relief in terms of reduction in both subjective and objective severity of incontinence, but gave up because of nuisance side effects and difficulty handling the device. The reverse is true of the FemAssist, where non-responders seem dissatisfied because of poor efficacy with specific activities and overall control of "wetness". Women with greater initial QoL impairment and more bothersome urinary symptoms with a greater incontinence impact are less likely to respond to treatment and more likely to discontinue device use. In this way the urinary symptom specific questionnaire can be used to predict women in whom devices are most likely to be effective. This is a useful observation. Continence devices should still be offered to all women with quality of life impairment resulting from GSI providing there are no contraindications because they work in the majority. However, targeting women with greater QoL impairment for more definitive treatment is likely to be more beneficial as containment of incontinence is unsatisfactory.

Bias

There are many potential biases in responding to the KHQ and it is probable that the data collected from the women who did attend does not accurately represent the total population of women with GSI. Thirty-four (33.7%) women failed to complete the study, possibly as a result of the additional appointments required for its completion. Consequently women who were dry with device use or for whom a hospital appointment was inconvenient may have declined to attend. As a result a greater proportion of those who did respond to repeat QoL questioning are likely to have had residual problems to discuss and therefore poorer overall QoL.

Women with greater problems and presumably greater quality of life impairment are more likely to want to be seen and women who are more anxious about the investigation and their future management are also more likely to be seen than women who are only slightly inconvenienced by their urinary symptoms. Elderly women for whom travel to the hospital may be difficult and employed women who find it hard to take time off from work are also possibly underrepresented in this group. Almost all of the women who attend our unit however, have significant urinary symptoms, by the very fact that they have sought help in the first place.

In addition, many women responding to the KHQ register vocational impairment as one of the problems caused by their urinary symptoms and it is documented that a considerable number took time off from work to attend the hospital for follow-up. It is more likely therefore that these women are under represented in the follow-up phase of the study. Absence from work and inconvenience of travel to Kings would be greater after treatment, especially if this had been successful, when there would be little additional benefit for the patient. Women who were cured or improved by the devices after one month and had few problems did not attend for final follow-up and were under represented in the final phase of the study.

Thus, the improvement in quality of life documented with the KHQ is likely to underestimate the true improved quality of life gained by use of the device for all the women attending for the initial assessment.

URINARY SYMPTOMS (KHQ)

There is a significant reduction in the "bothersome" scores for the symptom of stress incontinence as assessed using the KHQ after therapy with either device also showing

a reduction in the modal score from three to one. There is also a trend to a reduction in the mean "bothersome" scores for the symptom of frequency. Subjects not having to ensure they keep their bladders empty to reduce the risk of an incontinence episode may explain this.

ADVERSE EVENTS

The weighing up of the risks of treatment against the risks of no intervention is a question of risk balancing. The risks that the individual is prepared to accept will be in proportion to the expected benefits gained in terms of improvements in quality of life. Women with urinary incontinence already run and presumably accept the risks of perineal discomfort and embarrassing leakage as a result of their condition and I expect this has a part to play in the acceptability of the problems experienced with the use of continence devices.

Despite the Reliance device being a urethral insert its design is sufficiently effective that migration into the urethra or bladder is not a problem, as might be anticipated.

Frank haematuria is not observed in the absence of infection with use of either device. Overuse of the FemAssist device is likely to lead to spotting of blood as a result of the suction effect. The Reliance device does not seem to irritate the surrounding area as much to produce this effect. However, the reverse is true of urethritis, this being more common in the Reliance group. It would be incorrect to state that urethritis was a minor problem. It certainly occurred infrequently but when it did, it was distressing for the patients concerned.

Bacteriuria

Asymptomatic bacteriuria is a common occurrence in both groups of device users but its clinical significance remains unclear. Experience in CISC provides insight into the expected adverse events with repeated daily introduction of a catheter-like device into the urethra. Thus the circumstances under which it occurs with the Reliance device is easily understood. The indwelling "plug" and its placement may provide a microenvironment conducive to the growth of bacteria and infection.

This does not explain a similar incidence with a non-insurtable suction device like the FemAssist. It may be that the FemAssist, by way of meatal occlusion and coaptation of the device in close proximity with the walls of the urethra permits ascending microbiological invasion of the bladder increasing the susceptibility to infection.

URINARY TRACT INFECTION

The low prevalence rate of positive urine cultures compares favourably to age-specific historical figures of 10 – 38% [13]. The rate of positive urine cultures (10.3% Reliance, 11.4% FemAssist) is similar in both groups of device users, and for the Reliance, matches that observed in other studies [8] (Table 14.3). However, the rate of infection in this study of FemAssist users is much higher than observed by other investigators [14 15]. This is perplexing and surprising. We can offer little explanation other than the possibility that, to get better containment of leakage, these women utilised a greater amount of device manipulation with consequent infection. The rate of infection fell over the duration of the study and one may infer that before women become more proficient in device insertion and avoiding contamination, the initial "learning curve" accounts for these prevalent early infections. With practice, the degree of manipulation required for device placement and removal decreases, and as does the risk of cystitis. None of the subjects suffered any sequelae of their positive urine cultures.

Urinary tract infection with use of continence devices	
Device	**UTI (%)**
Adhesive continence patch (North et al 1998) [1]	0%
CapSure(Bellin et al 1998) [2]	3.5%
Introl (Foote et al 1996) [3]	15.4%
FemAssist (Versi et al 1998) [14]	0%
FemAssist (Rabin et al 1997) [15]	0%
FemAssist (present study)	**11.3%**
Reliance (Staskin et al 1996) [8]	11%
Reliance (Pigne et al 1997) [9]	14%
Reliance (Miller et al 1996) [10]	30%
Reliance (present study)	**10.4%**

Table 14.3 The rates of urinary tract infection with device use reported in the literature in comparison with this study.

Erythema

A small discrete area of erythema under the area of contact with the device is to be expected in all women using the FemAssist. These are anticipated due to the wider area of contact and suction mechanisms of the device. Once the device is removed this pressure effect resolves after 5 – 10 min with no long term sequelae. The suction effect of this device is also very likely to result in small mild petechial haemorrhages under the points of contact with the skin. These clear spontaneously upon cessation of device use and require no treatment.

The meatal plate of the Reliance device only very occasionally causes skin irritation but is more likely to result in the patient discontinuing use. Petechial haemorrhages are not manifest in Reliance device users.

The observations suggest that the FemAssist device may cause a change in the soft tissue microenvironment with which it is in contact as well as a deeper effect beyond the surface of contact due to the vacuum or suction effect of the device. This may lead to congestion in the tissues, bruising and petechial haemorrhages. In this respect the FemAssist device is comparable to other external adhesive devices, such as

transdermal oestrogen patches, which have approximately a 10% incidence of skin irritation.

What is unclear is whether or not women with atrophic genital changes should be encouraged to use vaginal oestrogen cream to reduce the risk of mucosal damage. This advice does seem inherently sensible but requires further appraisal.

As a group few women experienced any adverse physical side effects while wearing either device. The incidence of adverse events is well within the range expected with other commonly accepted self-catheterisation techniques and continence aids. Additionally, these events tend to decrease in frequency over time so devices are generally well tolerated, which is an important attribute for long term treatment.

In women having long term catheterisation, bacteriuria should be expected and extended prophylaxis is not only expensive but is also likely to result in the selection of resistant organisms [16]. Hence, antimicrobial treatment of asymptomatic bacteriuria is probably not justified in these subjects and should be reserved for those in whom it is clinically indicated.

COMPLIANCE

When estimating the likely benefit of continence devices, we must also consider the likelihood that patients will comply with the intervention. This trial has incorporated certain compliance-improving strategies not applied in routine clinical practice. For example, all women regularly consulted a clinician with an interest in continence and its management. Hence, the results of this study may have overestimated the benefit of continence devices that may be obtained in a routine clinical setting without such intensive guidance, education and support. Any measure of the clinical benefit of an intervention such as continence devices may vary considerably in different trials of the same or similar therapy because of different patient populations, trial designs or chance. Differences may have occurred because therapy was evaluated in a setting designed to maximise compliance rather than as part of routine patient care [17]. The clinical trial was also of finite duration and, because the benefits of treatment change with time, one can only provide suggestions about the consequences of continuing therapy in the long run.

PATIENT PREFERENCE

One of the guiding principles of economics is that individuals are assumed to be the best judges of their own welfare – people know what is good for them. This idea is not always a central theme in the traditional paternalistic model of medicine. The patient relies on the doctor's expertise for information. But where treatment choices exist it would appear that clinical decision-making might be improved if patient preferences were elicited. The effectiveness of many health programs is shifting emphasis and becoming increasingly dependent upon the willingness of individuals to accept a more active role in caring for their health. There are many factors which influence women to comply with preventative behaviour for urinary incontinence. These may include the value placed by an individual on a particular goal and the individual's estimate of the likelihood that a given action will achieve that goal. It is difficult to measure the individual's desire to avoid urinary incontinence and the belief that devices can prevent urinary incontinence and by compliant action, will reduce the threat.

Women are more likely to use either device primarily during activities associated with urine loss rather than for casual use for occasional incontinence. All the same, as incontinence affects each individual differently, some women use devices for occasional incontinence which is associated with a large disruption to their quality of life.

COST

During the 6 months period women used approximately 948 FemAssist devices. This was at a total cost of £7,110 and approximately £57.34 per patient.

During the 6 months period women used approximately 12,981 Reliance devices. This was at a total cost of £12,981 and approximately £127.26 per patient. This represents an increase in cost of £69.92 or2.2 times the cost of using the FemAssist device. This is only a very crude costing, but does give some indication of the expense which may be incurred by the individual woman.

RELATIONSHIP BETWEEN INPUTS AND OUTCOMES

The evidence from the trial supports the alternative hypothesis that devices result in a reduction in the symptom of stress incontinence but this may be difficult to explain. Inputs from other mechanisms and from informal sources may also be important. One has to acknowledge the likelihood that systematic variations in the pattern of inputs which are outside the control of the study may have a direct bearing on the outcome and are a potential source of bias. Did follow-up achieve better outcomes because patients were reviewed and instructed as appropriate or because compliance was encouraged? In this thesis I tried to go beyond the erudite demonstration of statistical associations between device use and reduction in PWT gains or incontinence episodes. The patient's subjective assessment of the device and the use of a urinary incontinence specific quality of life instrument to measure the impact of these devices greatly help to specify what occurs at the intermediate steps between the input and outcome.

The study has demonstrated that there is a strong association between both the improved outcome and device utilisation. Also, the Reliance device is associated with a significantly greater reduction in these parameters than the FemAssist device. It may be argued that the associations of good clinical outcome with device usage were in reality secondarily associated with other factors. Statistical tests suggest that the probability is low that the observed associations are chance occurrences so consequently have a high probability of being true associations. The associations may be spurious and a product of the way in which the investigation was carried out. I tried to ensure, through rigorous study methodology and design with care to reduce bias, that like was being compared with like. There are certain criteria which help to infer that the results of efficacy and safety are due to device usage.

Plausibility

Greater weight can be given to the results as it fits in with what is known about the pathology of GSI and about the effects of the same and similar devices in the management of women with stress incontinence, as published in the literature.

Consistency

When various investigators working in different populations carried out studies, similar results of device efficacy and safety were obtained as noted in chapter four. This demonstrates a certain consistency in the outcome of this trial with regard to the effects of the devices. The large differences in the objective outcome measures found in both groups from baseline at study conclusion are consistent with the findings of others, supporting results that reflect real differences in pre-treatment status rather than group differences as a result of bias.

Strength

There is a marked statistical difference in the outcome measures compared to when not using a device. This is clinically significant and has a beneficial impact on the subjects. Accordingly, this confers a degree of strength to the association with clinical improvement as a consequence of device usage.

Conclusion

- Quality of life measures would appear to be ideally suited for use in clinical trials to assess the efficacy of new treatments for containment of urinary incontinence such as continence devices.
- Quality of life scores significantly improve following treatment of urinary incontinence in women who are subjectively cured or improved by use of a continence device.
- In the context of a clinical trial, objective improvements in pad weight tests and incontinence episodes on the urinary diary although highly desirable are still of secondary important to the improvement in quality of life conferred on the women treated.
- Many of the devices currently employed have a high degree of objective success. The benefits of new devices and continence aids may therefore best be measured by the difference in quality of life conferred.
- Measuring quality of life in women with incontinence is critical to understanding the full impact of the condition, and this prospective data may

be critical in establishing reliable estimates of levels of impairment that can be used for clinical decision making.

- In conditions like stress incontinence, in which general health perception is good and the likelihood of disease-related fatality is low, assessment of quality of life might lead to less invasive conservative therapies such as continence devices.
- The results of the study reveal that, using subjective and objective measures of efficacy and safety, both devices are effective in the containment of urinary leakage in women with GSI.
- The Reliance device is significantly superior to the FemAssist on several measures of efficacy. This may be attributed partly to the failure of the FemAssist but also to the potential superior efficacy of the Reliance.
- Although not tested in this study, devices may be an important alternative to absorbent products and other management strategies.
- Long-term studies of continence devices would be difficult to carry out and require determination and motivation from investigators and patients to persist with treatment, as patient attrition is a problem.
- The significant reduction in urine loss during device use compares favourably to other devices as assessed by the outcome measures.
- Stratification of the women into moderate or severe GSI confirms that the devices are equally effective for both these levels of severity of incontinence.
- Analysis of the women who withdrew from the study confirms device efficacy in this subgroup as well.

FUTURE

Urinary incontinence is not life threatening but is a quality of life issue with considerable impact upon the wellbeing of those who suffer. There is a growing awareness of what can be done to help the woman with stress incontinence and some important developments have occurred. There are an increasing number of continence clinics addressing the particular needs of women and a rising number of physiotherapists specialising in the management of stress incontinence. The establishment of various national continence organisations such as the ICS UK, the

Continence Foundation and the Kings Fund help to improve public awareness and professional education and also focus government and industry support. The ICS has also established the Continence Promotion Committee to address continence awareness and promotion around the world.

Independent continence is the preferred outcome. At the outset if this is not going to be rapidly achieved then social continence should be established. It may now be possible to develop various strategies to shift the patient to a state of independent continence. Having achieved this with the use of devices, we can expect an improved state of wellbeing and self-esteem and overall better quality of life for some women.

As medicine and health care move towards the 21st Century, treatment would appear to be increasingly less about extending the length of life and more about improving its quality. Future incremental gains in health will be purchased at the price of increased risk-taking. This is not to suggest that management of incontinence with devices is risky, but new innovations carry new risks.

Factors likely to improve compliance and result in successful device utilisation

- Team support
- Correct instructions
- Enthusiasm, attitude in carers?
- Well trained carers
- Patient motivation and compliance.
- Interest, support, reassurance and review by carers.

Attitudes, which accept urinary incontinence as a personal failing, must be changed. All women can be helped to manage their incontinence through education and information about the condition and the therapies available. Their quality of life can be expected to improve with successful continence management but this depends on patient motivation and compliance.

Research in urinary incontinence in adult women remains impaired by lack of standardisation of outcome variables. The use of primary and secondary outcomes on different areas or domains should help overcome some of these difficulties. Success in this regard will not only enhance knowledge of actual treatment strategies but also

stimulate the development of new ones. One of the benefits of evaluation is to enable improvements in strategies in the management of urinary incontinence and with respect to the future introduction of similar initiatives into continence device research. This can be viewed as ensuring the presence of a "feedback loop" linking evaluation findings to future plans so that the lessons learned can be incorporated into the design of the new programs.

WHY NEW CONTINENCE AIDS?

DO INCONTINENT WOMEN NEED DEVICES?

Evidence about consumers' perspectives on continence services is growing [18]. So much so that political pressure has been brought to bear and the Department of Health has sponsored public awareness campaigns in both 1994 and 1995. Also, with an increasingly ageing population and increasing public awareness, demands for the continence service look set to increase in the future.

The need for health care is defined as "the appropriate level of provision of health care interventions that is both effective and desired by the population"[19]. With soaring costs of health and long term care, the health service providers need to develop home care policies which provide high quality, low cost care in the home and community. This requires a multidisciplinary approach based around the primary care physician and community health care workers. New types of treatment are emerging, hence, it is highly desirable to widen the scope of management to a program of home and community care. Women seek medical advice when their symptoms cause discomfort, distress, inconvenience, disturbance and departure from their normal state of health and interference with their quality of life. The aim of treatment is to alleviate suffering, remove symptoms and return women to a normal state of health. With these goals in mind, considerable interest has emerged in the use of devices to contain the symptoms of stress incontinence.

In many countries the budget for incontinence disposables has proved very difficult to control in many areas. It has been suggested that implementing research findings to improve clinical practice in managing urinary incontinence should result in significant cost savings [20]. It is difficult to generalise concerning the need for further development of continence devices, given the varying stages of development at present. It is likely however, that the most useful developments in coming years will

arise from work which builds on existing devices. There is considerable scope in many cases for refinement of design, improved materials with a softer consistency and of longer shelf life and adaptations to particular situations.

WHY ARE AIDS NECESSARY?

- Incontinence may not resolve with treatment
- Intractable incontinence
- Contain and disguise incontinence
- Provide symptom relief and better quality of life
- Comfort and dignity
- Application in primary health care

In 1981, the Engineering Board of the Scientific Research Council in England developed a list of biotechnological research priorities. Since alleviation of human hardship was a major goal, the following criteria were used to determine priorities[21]:

- An identified and significant medical need that is not being met because of the shortcoming in existing aids
- A lack of research effort aimed at developing better aids
- The availability of scientific and/or technical knowledge to make significant progress at a reasonable cost
- Acceptable costs of implementation
- The presence of organisational apparatus for implementation

Below is a list of the types of products they deem should be investigated.

PRODUCT TYPES

- Absorbent products
- Collection devices
- Catheters
- Occlusive devices
- Toilets and toilet substitutes
- Odour control

Previously developed external urinary incontinence devices for women had been described but assessment of efficacy was difficult, since prior reports frequently lacked detail. They concluded that there was no satisfactory wearable collection device for women who had urinary incontinence so development was given a high priority.

The concept of need is central to the provision of continence care in women as it defines the objectives of care. Needs can be defined in a variety of different ways and perspectives. Measures of need incorporate value judgements about what should be accepted as appropriate goals. Needs can be assessed against some ideal standard. They can be defined in terms of a minimum level below which women should not fall and can be assessed by reference to comparisons with standards achieved by other individuals. The comparative approach offers a compromise between largely indefinable ideals and highly restrictive minimum standards. Thus, the need for continence devices can be defined in terms of the standards known to be achieved by comparable methods of containment of urinary leakage (i.e. pads, pants, conservative and surgical therapy). In selecting an appropriate measure of the need for continence devices, one must consider whose perspective and definition of need is important. Traditionally, judgements about needs of incontinent women have been regarded as the province of the medical profession. As treatment options for incontinence expand and evolve, patients are playing a bigger role in management of their condition than ever before. Some measures rely on the individual's own perception of need, a sense of discrepancy between being incontinent and what ought to be (dry). It is the expression of these needs that prompts the patient to seek help.

Many health care professionals who treat female urinary incontinence (urologists gynaecologists and general practitioners) continue to recommend management options they consider less than effective [22]. It has been well documented that women with persisting incontinence do not use optimal aids for protection. For example, in one study 20% of clinicians recommended the use of absorbent pads, while only 8% rated them as the most effective option [23]. Also, almost half of the incontinent women were dissatisfied with the first treatment recommended by their physician. Given a choice between behavioural techniques, pharmacological agents and surgery, 67% of those with stress incontinence initially chose non-surgical treatment options to help self-manage their incontinence [24]. However, clinicians and patients alike must recognise that unlike surgery, where dryness is maintained without patient

participation, the use of mechanical devices requires active participation to maintain dryness.

It is not possible to perform a double blind RCT to assess the efficacy and safety of these devices. This trial was not only a comparative study where the patients acted as their own controls, but was also carried out to assess the applicability of two contemporary continence devices and patients response to their use. This study demonstrates that the Reliance and FemAssist have complementary benefits and the efficacy of both devices in reducing stress incontinence coupled with a benevolent side-effect profile commends these continence aids for the long-term treatment of women with GSI. This would offer strong support to the need for different types of devices to satisfy patient preferences, possibly utilising different mechanisms of action to limit side effects. Quality of life measurement prior to treatment would seem an ideal method for selecting women who are most likely to benefit from continence devices. Because the diagnosis of GSI was clearly made in compliance with established criteria, generalisation and application of the results to a broader population of all women with incontinence must be considered cautiously. But a single study's results cannot form the basis of clinical practice. Our clinical knowledge base comes from the results of trials by different research groups, working with different populations possibly using different methods. The closest approximation to the efficacy of continence devices is likely to come from an amalgam of the evidence gained from this and previous trials utilising these devices in women with stress incontinence. The results of this study and the others identified support and advocate continued development and implementation of research into new aids to continence.

References

[1] North B. A disposable adhesive patch for stress urinary incontinence. Fam Med 1998;30(4):258-264.

[2] Bellin P, Smith J, Pok W et al. Results of a multicentre trial of the CapSure [Re/Stor] continence shield on women with stress urinary incontinence. Urology 1998;51:697-706.

[3] Foote A, Moore K, King J. A prospective study of the long term use of the bladder neck support prosthesis. Neurourol Urodynam 1996;15(4):404-406.

[4] Hahn I, Milsom I. Treatment of female stress urinary incontinence with a new anatomically shaped vaginal device (Conveen Continence Guard). Br J Urol 1996;77:711-15

[5] Hahn I, Milsom I. Treatment of female stress urinary incontinence with a new anatomically shaped vaginal device (Conveen Continence Guard). Br J Urol 1996;77:711-15

[6] Prashar S, Moore K, Bryant C, Powell C. The urethral occlusive device for the treatment of urinary incontinence: changes in quality of life.

[7] Tincello D, Bolderson J, Richmond D. Preliminary experience with a urinary control device in the management of women with genuine stress incontinence. Br J Urol 1997;80:752-56.

[8] Staskin D, Barendam T, Miller J et al. Effectiveness of a urinary control insert in the management of stress urinary incontinence: early results of a multicentre study. Urology 1996;47(5):629-636.

[9] Pigne A, Bitker M, Cotelle-Bernede O et al. Reliance urinary control insert – result of a French multicentre study. Int Urogynecol J 1997;8(1):8128.

[10] Miller J, Barendam T. Treatment with the Reliance Urinary Control insert: one year experience. J Endourol 1996; 10(3):287-92.

[11] Lapides J, Ajemian E, Bruce H, Lichward J, Breakey B. Physiopathology of stress incontinence. Surg, Gynecol Obstet. 1960;3:224.

[12] Bruschini H, Schmidt R, Tanagho E. Effects of urethral stretch on urethral pressure profile. Invest Urol 1977;15:107.

[13] Sourander L, Kasanew A. A five year follow-up of bacteriuria in the aged population. Gerontol Clin. 1972;14:274-281.

[14] Versi E, Griffiths D, Harvey MA. A new external urethral occlusion device foe female urinary incontinence. Obstet Gynecol 1998; 92: 286-91.

[15] Rabin J. The FemAssist: a new device for the treatment of female urinary incontinence. Int Urogynecol J 1997;8(1):S1.

[16] Nicolle LE. Prevention and treatment of urinary catheter related infections in older patients. Drugs and Ageing 1994;4(5):379-91.

[17] Sackett D, Gent M. Controversy in counting and attributing events in clinical trials. N Engl J Med 1979;301:1410-2.

[18] NHS Executive, 1994. Incontinence, Citizens charter and NHS Executive. F50.042 1715 IP 15K. December 1994

[19] Frankel S, Williams M, Nanchahal K, Coast J. Epidemiologically based needs assessment. Total hip and total knee joint replacement. Bristol : Healthcare evaluation Unit, 1990

[20] Agency of Health Care Policy and Researcy, 1992. Urinary incontinence in adults: Clinical practice guidelines AHCPR, US Department of Health and Human Services, Rockville USA.

[21] Cottenden A, Stocking B, Jones N, Morrison S, Rothwell R. Biomedical engineering priorities for research in external aids. J Biomedical Engineering 1981;3:325-8

[22] National Survey. Bladder Health Council of the American foundation for Urologic Disease. PRN. Dec 1995.

[23] Seim A, Sivertsen B, Eriksen B, Hunskaar S. Treatment of urinary incontinence in women in general practice: observational study. Br Med J, 1996;312:1459-62.

[24] Diolno A, Yahico M. Preference compliance and initial outcome of therapeutic options chosen by female patients with urinary incontinence. J Urol 1995;154:1727-30.

APPENDICES WITH RAW DATA

HEALTH STATUS QUESTIONNAIRE (SF-36)

For office

THE FOLLOWING QUESTIONS ASK FOR YOUR VIEWS ABOUT YOUR HEALTH, HOW YOU FEEL AND HOW WELL YOU ARE ABLE TO DO YOUR USUAL ACTIVITIES. IF YOU ARE UNSURE ABOUT HOW TO ANSWER ANY QUESTION, PLEASE GIVE THE BEST ANSWER YOU CAN AND MAKE ANY COMMENTS IN THE SPACE AVAILABLE AFTER QUESTION 10.

Please tick one

1. In general would you say your health is:

- Excellent ○
- Very good ○
- Good ○
- Fair ○
- Poor ○

2. Compared to one year ago, how would you rate your health in general now?

- Much better now than one year ago ○
- Somewhat better now than one year ago ○
- About the same ○
- Somewhat worse now than one year ago ○
- Much worse now than one year ago ○

For offi

HEALTH AND DAILY ACTIVITIES

3. **The following questions are about activities you might do during a typical day. Does your health limit you in these activities? If so, how much?**

Please tick one circle on each line

	Yes, limited a lot	Yes, limited a little	No, not limited at all
a. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	○	○	○
b. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling or playing golf	○	○	○
c. Lifting or carrying groceries	○	○	○
d. Climbing several flights of stairs	○	○	○
e. Climbing one flight of stairs	○	○	○
f. Bending, kneeling or stooping	○	○	○
g. Walking more than a mile	○	○	○
h. Walking half a mile	○	○	○
i. Walking 100 yards	○	○	○
j. Bathing and dressing yourself	○	○	○

4. **During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?**

Answer Yes or No to each question

	YES	NO
a. Cut down on the amount of time you spent on work or other activities	○	○
b. Accomplished less than you would like	○	○
c. Were limited in the kind of work or other activities	○	○
d. Had difficulty performing the work or other activities (e.g. it took extra effort)	○	○

For office

5. **During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?**

Answer Yes or No to each question

	YES	NO	
a. Cut down on the amount of time you spent on work or other activities	○	○	☐
b. Accomplished less than you would like	○	○	☐
c. Didn't do work or other activities as carefully as usual	○	○	☐

6. **During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours or groups?**

Please tick one

Not at all	○	☐
Slightly	○	☐
Moderately	○	☐
Quite a bit	○	☐
Extremely	○	☐

7. **How much bodily pain have you had during the past 4 weeks?**

None	○	☐
Very mild	○	☐
Mild	○	☐
Moderate	○	☐
Severe	○	☐
Very severe	○	☐

8. **During the past 4 weeks, how much did pain interfere with your normal work (including work both outside the home and housework)?**

Not at all	○	☐
A little bit	○	☐
Moderately	○	☐
Quite a bit	○	☐
Extremely	○	☐

For office

YOUR FEELINGS

9. **These questions are about how you feel and how things have been with you <u>during the past month.</u>** *(For each question, please indicate the one answer that comes closest to the way you have been feeling)*

Please tick one circle on each line

How much time during <u>the past month</u>:	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time	
a. Did you feel full of life?	○	○	○	○	○	○	□
b. Have you been a very nervous person?	○	○	○	○	○	○	□
c. Have you felt so down in the dumps that nothing could cheer you up?	○	○	○	○	○	○	□
d. Have you felt calm and peaceful?	○	○	○	○	○	○	□
e. Did you have a lot of energy?	○	○	○	○	○	○	□
f. Have you felt downhearted and low?	○	○	○	○	○	○	□
g. Did you feel worn out?	○	○	○	○	○	○	□
h. Have you been a happy person?	○	○	○	○	○	○	□
i. Did you feel tired?	○	○	○	○	○	○	□
j Has your <u>health limited your social activities</u> (like visiting friends or close relatives)?	○	○	○	○	○	○	□

For offic

HEALTH IN GENERAL

10. Please choose the answer that best describes how true or false each of the following statements is for you.

Please tick one circle on each line

	Definitely true	Mostly true	Not sure	Mostly false	Definitely false
a. I seem to get ill more easily than other people	○	○	○	○	○
b. I am as healthy as anybody I know	○	○	○	○	○
c. I expect my health to get worse	○	○	○	○	○
d. My health is excellent	○	○	○	○	○

Comments

Medical Care Research Unit, Department of Public Health Medicine,
University of Sheffield Medical School, Beech Hill Road, Sheffield, S10 2RX

KING'S HEALTH QUESTIONNAIRE

1993

Name _____

Age _____ **years**

Todays date ___/___ **199**

Office us

How would you describe your health at present ?

Please tick one answer

Very good	○
Good	○
Fair	○
Poor	○
Very poor	○

/5

How much do you think your bladder problem affects your life ?

Please tick one answer

Not at all	○
A little	○
Moderately	○
Alot	○

/4

We would like to know what your bladder problems are and how much they affect you. From the list below choose ONLY THOSE PROBLEMS that you have at present.

How much do they affect you ?

	A Little	Moderately	Alot	
FREQUENCY; going to the toilet very often.	○	○	○	☐
NOCTURIA; getting up at night to pass urine.	○	○	○	☐
URGENCY; a strong and difficult to control desire to pass urine.	○	○	○	☐
URGE INCONTINENCE; urinary leakage associated with a strong desire to pass urine.	○	○	○	☐
STRESS INCONTINENCE; urinary leakage with physical activity eg coughing, sneezing, running.	○	○	○	☐
NOCTURNAL ENURESIS; wetting the bed at night.	○	○	○	☐
INTERCOURSE INCONTINENCE; urinary leakage with sexual intercourse.	○	○	○	☐
FREQUENT WATERWORKS INFECTIONS;	○	○	○	☐
BLADDER PAIN;	○	○	○	☐
OTHER SPECIFY; _____	○	○	○	☐

Please turn the page

Office use ☐ + ☐ + ☐

Below are some daily activities that can be affected by bladder problems. How much does your bladder problem affect you ?
We would like you to answer every question. Simply tick the circle that applies to you.

ROLE LIMITATIONS

	Not at all	Slightly	Moderately	Alot
To what extent does your bladder problem affect your household tasks (eg cleaning, shopping etc)	○	○	○	○
Does your bladder problem affect your job, or your normal daily activities outside the home?	○	○	○	○

PHYSICAL/SOCIAL LIMITATIONS

	Not at all	Slightly	Moderately	Alot
Does your bladder problem affect your physical activities (eg going for a walk, run, sport, gymn etc)?	○	○	○	○
Does your bladder problem affect your ability to travel?	○	○	○	○
Does your bladder problem limit your social life ?	○	○	○	○
Does your bladder problem limit your ability to see/visit friends ?	○	○	○	○

PERSONAL RELATIONSHIPS

	Not applicable	Not at all	Slightly	Moderately	Alot
Does your bladder problem affect your relationship with your partner?	○	○	○	○	○
Does your bladder problem affect your sex life?	○	○	○	○	○
Does your bladder problem affect your family life?	○	○	○	○	○

Please turn the page

Office use □□ □□ □□ □□□

EMOTIONS

	Not at all	Slightly	Moderately	Very mu
Does your bladder problem make you feel depressed?	○	○	○	○
Does your bladder problem make you feel anxious or nervous?	○	○	○	○
Does your bladder problem make you feel bad about yourself?	○	○	○	○

SLEEP / ENERGY

	Never	Sometimes	Often	All the time
Does your bladder problem affect your sleep ?	○	○	○	○
Do you feel worn out / tired?	○	○	○	○

Do you do any of the following?;

If so how much ?	Never	Sometimes	Often	All the time
Wear pads to keep dry?	○	○	○	○
Be careful how much fluid you drink?	○	○	○	○
Change your underclothes when they get wet?	○	○	○	○
Worry in case you smell?	○	○	○	○

Office use ☐☐☐ ☐☐ ☐☐☐☐

THANKYOU, NOW CHECK THAT YOU HAVE ANSWERED ALL THE QUESTIONS

King's Health Questionnaire, Version 7.

RAW DATA

AGE

The age distribution at study inclusion for each group is shown in Table A1.

Age (years) distribution at study inclusion							
Age Groups	**21-30**	**31-40**	**41-50**	**51-60**	**61-70**	**71-80**	**Total**
Reliance	1 (2%)	8 (16.7%)	21 (43.7%)	15 (31.3%)	3 (6.3%)	0	48
FemAssist	1 (1.9%)	10 (18.9%)	21 (39.6%)	16 (30.2%)	4 (7.5%)	1 (1.9%)	53

Table A1 The patient age distribution at study inclusion for each group.

EASE AND COMFORT OF DEVICE USE

The patient rating of ease of device placement and comfort of use recorded at each follow-up visit for each group is recorded in Table A2 and Table A3 respectively.

Patient rating of "ease" of placement of each device Over the period of the trial						
	1 Month		**3 Months**		**6 Months**	
Score	Reliance	FemAssist	Reliance	FemAssist	Reliance	FemAssist
1	4	8	6	14	5	17
2	23	24	14	23	15	16
3	12	10	8	2	10	2
4	4	3	1	2	1	1
5	1	2	0	0	0	0
Missing	4	6	19	12	17	17

Table A2 Patient ratings on ease of device placement recorded at each follow-up visit for each group. (Score 1= Very easy, Score 5= Extremely difficult)

Patient rating of "comfort" of device use Over the period of the trial						
	1 Month		**3 Months**		**6 Months**	
Score	Reliance	FemAssist	Reliance	FemAssist	Reliance	FemAssist
1	2	8	5	12	5	12
2	12	18	12	22	11	20
3	23	13	11	6	13	3
4	5	6	0	1	2	01
5	2	2	1	0	0	0
Missing	4	6	19	12	17	17

Table A3 Patient ratings on comfort of device use recorded at each follow-up visit for specific groups. (Score 1= Very comfortable, Score 5= Extremely uncomfortable)

CONTROL OF INCONTINENCE WITH DEVICE USE

ASSESSMENT OF SUBJECTIVE DEGREE OF DRYNESS

The baseline severity of wetness for each group, at each stage of assessment, is shown in Tables A4, and A5.

Baseline severity of "wetness" for each activity Of women in individual groups								
Score	**Rel**	**Fem**	**Rel**	**Fem**	**Rel**	**Fem**	**Rel**	**Fem**
	Sitting/lying		**Standing**		**Walking**		**Lift/bending**	
1	17	19	11	18	5	8	2	0
2	11	16	14	16	13	14	2	2
3	17	18	15	19	14	14	16	15
4	3	0	8	0	14	17	19	22
5	0	0	0	0	2	0	9	14

Table A4 The scoring of the degree of "wetness" or the severity of incontinence as assessed by the women in each group on entry to the trial for the activities of sitting/lying, standing, walking, lifting and bending. [(1 = no urine loss, 5 = severe loss) Rel = Reliance group, Fem = FemAssist group]

Baseline severity of "wetness" for each activity of women in individual groups						
Score	**Rel**	**Fem**	**Rel**	**Fem**	**Rel**	**Fem**
	Low impact Exercise		**High impact Exercise**		**Cough/sneeze/ Laugh**	
1	2	0	0	0	1	0
2	1	2	0	2	1	1
3	6	11	0	11	2	12
4	22	24	5	22	4	22
5	17	16	40	18	40	18

Table A5 The scoring of the degree of "wetness" or the severity of incontinence as assessed by the women in each group on entry to the trial for the activities of low impact exercise, high impact exercise and coughing/sneezing/laughing.

PATIENT RETED DRYNESS WITH DEVICE USE

Patient rated dryness for the activities tested at the one-month visit are recorded in tables A6 and A7.

1-Month severity of "wetness" scores for each activity tested in individual groups								
Score	**Rel**	**Fem**	**Rel**	**Fem**	**Rel**	**Fem**	**Rel**	**Fem**
	Sitting/lying		**Standing**		**Walking**		**Lift/bending**	
1	42	47	42	44	40	30	40	27
2	0	0	0	3	2	6	2	8
3	0	0	0	0	11	0	0	0
4	0	0	0	0	0	0	0	0
5	0	0	0	0	0	0	0	0

Table A6 The scoring of the degree of "wetness" or the severity of incontinence as assessed by the women in each group for the activities of sitting/lying, standing, walking, lifting and bending. [(1 = no urine loss, 5 = severe loss) Rel = Reliance group, Fem = FemAssist group]

1-Month severity of "wetness" scores for each activity tested in individual groups						
Score	**Rel**	**Fem**	**Rel**	**Fem**	**Rel**	**Fem**
	Low impact Exercise		**High impact Exercise**		**Cough/sneeze/ Laugh**	
1	38	22	24	0	31	17
2	3	14	14	10	11	15
3	0	0	0	20	0	13
4	0	11	0	17	0	21
5	0	0	0	0	0	1

Table A7 The scoring of the degree of "wetness" or the severity of incontinence as assessed by the women in each group for the activities of low impact exercise, high impact exercise and coughing/sneezing/laughing.

Patient rated dryness for the activities tested at the three-month visit are recorded in tables A8 and A9.

3-month severity of "wetness" scores for each activity tested in individual groups								
Score	**Rel**	**Fem**	**Rel**	**Fem**	**Rel**	**Fem**	**Rel**	**Fem**
	Sitting/lying		**Standing**		**Walking**		**Lift/bending**	
1	29	41	29	38	27	31	27	31
2	0	0	0	3	2	6	2	6
3	0	0	0	0	0	2	0	1
4	0	0	0	0	0	2	0	2
5	0	0	0	0	0	0	0	0

Table A8 The scoring of the degree of "wetness" or the severity of incontinence as assessed by the women in each group for the activities of sitting/lying, standing, walking, lifting and bending. [(1 = no urine loss, 5 = severe loss) Rel = Reliance group, Fem = FemAssist group]

3-month severity of "wetness" scores for each activity tested in individual groups						
Score	**Rel**	**Fem**	**Rel**	**Fem**	**Rel**	**Fem**
	Low impact Exercise		**High impact Exercise**		**Cough/sneeze/ Laugh**	
1	27	26	12	5	21	19
2	2	10	14	15	8	20
3	0	2	0	17	0	2
4	0	3	0	0	0	0
5	0	0	0	0	0	0

Table A9 The scoring of the degree of "wetness" or the severity of incontinence as assessed by the women in each group for the activities of low impact exercise, high impact exercise and coughing/sneezing/laughing. [(1 = no urine loss, 5 = severe loss) Rel = Reliance group, Fem = FemAssist group]

Patient rated dryness for the activities tested at the six-month visit are recorded in tables A10 and A11.

6-month severity of "wetness" scores for each activity tested in individual groups								
Score	**Rel**	**Fem**	**Rel**	**Fem**	**Rel**	**Fem**	**Rel**	**Fem**
	Sitting/lying		**Standing**		**Walking**		**Lift/bending**	
1	31	36	31	34	29	33	31	33
2	0	0	0	2	2	5	1	3
3	0	0	0	0	0	5	0	0
4	0	0	0	0	0	0	0	0
5	0	0	0	0	0	0	0	0

Table A10 The scoring of the degree of "wetness" or the severity of incontinence as assessed by the women in each group for the activities of sitting/lying, standing, walking, lifting and bending. [(1 = no urine loss, 5 = severe loss) Rel = Reliance group, Fem = FemAssist group]

6-month severity of "wetness" scores for each activity tested in individual groups						
Score	**Rel**	**Fem**	**Rel**	**Fem**	**Rel**	**Fem**
	Low impact Exercise		**High impact Exercise**		**Cough/sneeze/ Laugh**	
1	29	28	17	5	19	20
2	2	2	13	1	12	18
3	0	6	0	30	0	3
4	0	0	0	0	0	0
5	0	0	0	0	0	0

Table A11 The scoring of the degree of "wetness" or the severity of incontinence as assessed by the women in each group for the activities of low impact exercise, high impact exercise and coughing/sneezing/laughing.

ASSESSMENT OF THE URINARY DIARY

INCONTINENCE EPISODES PER DAY

Incontinence episodes per day (IEPD) in women using the Reliance device.

Patient number	Baseline	1-month	3-months	6-months
1	5	2	2	1
2	5	2	2	1
3	4	1	1	
4	4	1	1	
5	5	1	1	1
6	5	2	1	
7	4	2	1	1
8	5	1	1	
9	5	1		
10	5	2		
11	6	2		
12	5	1	1	2
13	5	1		
14	5	1	1	1
15	6	2	2	2
16	5	2		1
17	5	1	1	1
18	5	1	1	1
19	5	2	1	1
20	5	2		
21	6	2		2
22	5	2	2	2
23	4	1	1	2
24	4	1	1	1
25	6	2	2	1
26	5	2		
27	4	2	1	1
28	5	2		
29	6	2	1	2
30	4		2	2
31	4			
32	6	1	1	1
33	4			
34	6	2	1	1
35	7	1		
36	6	2		1
37	4	1	1	1
38	5	2		
39	6	2	2	2

Patient number	Baseline	1-month	3-months	6-months
40	4	1	2	2
41	6	1		1
42	7	2	1	1
43	6	2	2	2
44	4			
45	6	2		
46	6			
47	6	2	1	1
48	4			

IEPD in women using the FemAssist device.

Patient number	Baseline	1-month	3-months	6-months
1	51	2	2	1
2	5			
3	4	2	2	1
4	5	2	2	
5	5	2	2	1
6	4	1	1	1
7	4	2	2	2
8	6	2	3	
9	4	2	2	1
10	6	1	2	1
11	6	2	2	0
12	5	1	2	1
13	7	2	2	1
14	5	1	1	0
15	5	1	1	0
16	4	1	2	
17	5	1	1	0
18	5	1		
19	5	1		
20	5	1	2	1
21	5	2	2	1
22	5	2	2	1
23	6	2	2	1
24	6	2	3	1
25	5	2	3	2
26	5	1	2	1
27	4	1	2	1
28	5	1	1	0
29	4	2	2	0
30	4	2	1	
31	4			
32	6	2	3	2
33	6	2	3	2
34	5	2	3	2
35	5	2	3	
36	5	2	1	1
37	4	2	2	1
38	5	1	2	1
39	4	2	2	1
40	4	2	2	1
41	4	1	2	1
42	4	1	3	2
43	5			

Patient number	Baseline	1-month	3-months	6-months
44	6	2	2	
45	5			
46	4			1
47	6	2	3	1
48	4			
49	6	1		
50	4			
51	4	2		
52	6			
53	8	2		

PADS USED OVER 5 DAYS

The number of pads used over 5 days in women using the Reliance device.

Patient number	Baseline	1-month	3-months	6-months
1	11	5	3	3
2	11	5	3	3
3	10	6	4	
4	10	6	4	
5	10	6	4	4
6	11	5	4	
7	12	5	3	3
8	11	5	3	
9	10	5		3
10	12	6		
11	9	6		
12	10	5	5	5
13	10	5		
14	10	4	3	3
15	10	4	3	3
16	12	4		3
17	12	6	3	3
18	11	5	4	4
19	12	3	3	3
20	11	5		
21	10	6		3
22	12	6	4	4
23	10	5	3	3
24	9	4	4	3
25	9	4	3	3
26	8	4		
27	8	4	4	4
28	8	5		
29	11	5	3	3
30	12		4	3
31	12			
32	12	6	3	4
33	11			
34	12	5	4	4
35	11	5		
36	10	5		
37	9	5	4	5
38	10	4		
39	10	6	3	4
40	11	5	5	4
41	12	5		4
42	11	4	4	3

Patient number	Baseline	1-month	3-months	6-months
43	10	6	5	4
44	10			
45	12			
46	12			
47	11	5	3	3
48	11	3		3

The number of pads used over 5 days in women using the FemAssist device.

Patient number	Baseline	1-month	3-months	6-months
1	10	5	5	4
2	10			
3	11			
4	10	5	4	5
5	9	6	4	
6	10	6	5	4
7	10	6	5	4
8	9	7	4	
9	10	6	5	4
10	8	5	5	5
11	11	5	5	
12	14	6	5	5
13	12	7	5	4
14	11	6	5	4
15	11	7	5	4
16	10	6	5	
17	9	6	4	4
18	11	6	4	4
19	9	5		
20	12	5	4	4
21	11	5	4	4
22	11	5	5	5
23	12	5	5	5
24	13	5	5	4
25	13	5	4	4
26	12	6	4	4
27	12	6	4	4
28	9	5	4	4
29	12	5	5	5
30	8	5	5	
31	10			
32	14	5	5	5
33	13	6	4	5
34	15	5	5	5
35	15	5	4	4
36	12	5	4	
37	14	9	4	4
38	11	7	5	4
39	10	6	4	4
40	10	6	5	5
41	11	6	5	5
42	11	7	5	5
43	12	7		

Patient number	Baseline	1-month	3-months	6-months
44	10	6	5	4
45	9			
46	12	5		
47	12	7	4	4
48	12			
49	11	5		
50	11			
51	12	7		
52	10			
53	11	5		

PAD WEIGHT TEST DATA

The pad weight test gains for women in the Reliance group.

Patient number	Baseline	1-month	3-months	6-months
1	44.1	0.2	0.6	0.7
2	14.8	1.3	1.6	1.7
3	37.5	2.1	1.9	
4	48.9	0.8	0.8	
5	37.2	0.8	1.2	0.5
6	11.1	0.1	0.9	
7	27.8	0.7	0.9	0.5
8	4.1	0.7	0.8	
9	11.4	0.1		0.2
10	58.6	2.1		
11	55.2	1.2		
12	40.3	3.5	2.1	2.1
13	3.8	0.6		
14	17.6	0.4	0.8	0.9
15	48.3	1.7	2.3	1.9
16	20	0.3		0.5
17	99.	0.3	4.6	0.1
18	1.2	0.2	0	2.5
19	1.3		0.6	0.6
20	21.1	0.5		
21	1.7	1.4		0.5
22	5.1	0.6	0.5	0.4
23	64.5	0.5	0.3	0.4
24	97.2	0.5	0.6	0.2
25	33.3	0.5	0.3	0.6
26	30.8	0.5		
27	32.4	0.3	0.5	0.6
28	1.2	0		
29	18.3	0.2	0	0.3
30	1.1		0.7	0.3
31	9.7			
32	52.5	0.5	0.2	0.4
33	63.6			
34	9.8	0.5	1.8	0.5
35	5	0.8		
36	36.6	0.1		0.4
37	19.3	0.8	0.5	0.9
38	21	0.4		
39	7.2	0.7	0.4	0.3
40	0.8	0.4	0.4	0.4

Patient number	Baseline	1-month	3-months	6-months
41	18.8	2.1		1.8
42	1.6	0.5	0.5	0.6
43	31.1	0.4	0.4	0.3
44	37.6			
45	20.7			
46	21			
47	56.7	1.1	0.8	0.8
48	37.4			0.9

The pad weight test gains for women in the FemAssist group.

Patient number	Baseline	1-month	3-months	6-months
1	40	2	3.5	3.5
2	20			
3	36	3	3	3
4	49	1.5	4	
5	38	3.5	4	4
6	16	0.5	4	4
7	33	3.5	3.5	4
8	5	3.5	3.5	
9	14	4	4	4
10	60	4.5	4	4
11	40	6	3	4
12	22	5	3	4
13	13	3.2	4	4
14	128	2.1	2	3
15	44	2.1	2	3
16	25	2	2	
17	100	2	2	3
18	2	5	4	3
19	15	4		
20	3	4	4	3.5
21	15	2	4	4
22	6	2	4	3
23	15	3	4	4
24	40	3	3	4
25	36	3.2	4	4
26	22	3.2	3	4
27	5	4.5	6	5.5
28	15	4	5	5
29	15	3	4	4
30	23	4	4	
31	6			
32	12	5	2.5	3
33	60	3	4	4
34	10	2.2	2	3
35	6	3.5	2	
36	33	3.5	4	4
37	19	3.8	4	4
38	22	3	2	2
39	15	3	4	4
40	12	3	2	2.5
41	22	5	4	4
42	12	3.5	2	2.5

Patient number	Baseline	1-month	3-months	6-months
43	33	3		
44	38	4.5	4	3
45	25			
46	25	4		
47	55	3	3.5	3
48	40			
49	31	2		
50	38			
51	34	2		
52	28			
53	35	4		

BASELINE QUALITY OF LIFE SCORES
RELIANCE GROUP
KINGS HEALTH QUESTIONNAIRE

The baseline Kings Health Questionnaire quality of life scores for women randomised to use the Reliance device (n=48) are illustrated below. The first column records the individual patients who are assigned a number, 1 to 48.

	GHP	Inimp	EL	RL	SL	S/E	PersL	Physl	SM
1	0	66.6	11.1	16.6	0	33.3	0	33.3	33.3
2	25	22.2	22.2	66.6	11.1	33.3	50	33.3	50
3	51	66.6	100	66.6	33.3	33.3	50	66.6	66.6
4	25	66.6	40	16	33.3	0	0	66.6	33.3
5	25	100	88.8	66.6	55.5	16.6	33.3	83.3	66.6
6	0	66.6	44.4	16	11.1	33.3	50	33.3	60
7	50	100	33.3	66.6	55.5	16.6	33.3	66.6	50
8	25	33.3	22.2	0	11.1	50	0	16.6	40
9	25	66.6	22.2	33.3	22.2	50	16.6	50	60
10	25	33.3	0	33.3	0	50	0	50	26.6
11	0	66.6	11.2	33.3	22.2	0	33.3	66.6	33.3
12	25	66.6	44.4	33.3	0	83	0	50	40
13	50	33.3	0	33.3	40	0	0	33.3	33.3
14	0	100	33.3	50	11.1	0	0	33.3	50
15	50	10	100	100	55.5	50	83.3	66.6	66.6
16	50	66.6	44.4	66.6	66.6	33.3	100	66.6	80
17	20	100	88.8	83.3	44.4	50	16.6	100	66.6
18	0	100	100	66.6	100	66.6	100	100	73.3
19	33.3	50	0	0	25	0	33.3	33.3	50
20	50	66.6	66.6	33.3	0	66.6	33.3	50	80
21	25	66.6	33.3	33.3	66.6	33.3	16.6	66.6	60
22	60	100	77.7	66.6	100	83	100	83.3	73.3
23	25	100	55.5	66.6	44.4	33.3	0	66.6	33.3
24	25	66.6	33.3	66.6	44.4	33.3	33.3	83.3	66.6
25	25	100	0	83.3	33.3	0	0	66.6	80
26	50	100	100	16.6	100	16.6	0	100	73.3
27	0	66.6	22.2	100	0	33.3	0	16.6	40
28	25	66.6	22.2	33.3	66.6	50	0	66.6	66.6
29	25	100	55.5	33.3	33.3	0	0	50	53.3
30	50	66.6	11.1	66.6	33.3	0	0	50	33.3
31	50	33.3	22.2	0	0	83.3	0	0	53.3
32	0	100	33.3	100	22.2	0	33.3	33.3	80
33	66.6	66.6	0	33.3	33.3	0	0	100	33.3
34	25	66.6	55.5	66.6	22.2	50	100	66.6	26.6
35	0	66.6	11.1	0	0	16.6	0	50	33.3
36	25	66.6	22.2	66.6	22.2	0	0	50	33.3
37	50	100	22.2	66.6	44.4	0	66.6	83.3	80
38	66.6	66.6	25	25	0	0	33.3	33.3	25

	GHP	Inimp	EL	RL	S/E	PersL	Physl	SL	SM
39	0	66.6	11.1	100	22.2	16.6	0	50	26.6
40	25	100	66.6	66.6	66.6	33.3	66.6	66.6	73.3
41	25	100	44.4	66.6	44.4	16.6	33.3	66.6	73.3
42	50	66.6	22.2	0	00	33.3	16.6	50	40
43	25	66.6	44.4	66.6	66.6	0	33.3	66.6	66.6
44	50	100	100	50	55.5	16.6	33.3	83.3	73.3
45	0	66.6	33.3	66.6	44.4	0	66.6	66.6	66.6
46	50	100	11.1	50	22.2	33.3	33.3	66.6	26.6
47	50	100	66.6	66.6	55.5	33.3	66.6	66.6	80
48	0	66.6	33.3	100	22.2	16.6	0	50	26.6

GHP= General health perception, Inimp= Incontinence impact, EL= Emotional limitation, RL= Role limitation, S/E= Sleep/energy disturbance, PersL= Personal limitation, PhysL= Physical limitation, SL= Social limitation, SM= Severity measures.

BASELINE QUALITY OF LIFE SCORES
RELIANCE GROUP
UK SHORT FORM 36
HEALTH SURVEY QUESTIONNAIRE

The baseline SF-36 questionnaire quality of life scores for women randomised to use the Reliance device (n=48) are illustrated below.

	PF	SF	PRL	ERL	MH	E/F	PAIN	GHP
1	70	75	25	66	63	55	66	59
2	65	65	43	61	60	50	60	58
3	63	66	33	55	66	60	66	55
4	66	66	30	60	63	55	60	57
5	65	66	40	60	60	60	61	58
6	75	75	20	70	66	60	67	65
7	72	77	20	70	65	60	70	60
8	65	65	22	61	60	57	69	62
9	72	77	28	68	60	57	68	64
10	70	76	38	70	60	51	64	63
11	64	65	40	58	55	48	71	65
12	71	70	43	70	66	55	60	60
13	66	74	44	71	62	50	66	59
14	68	70	25	66	58	46	66	58
15	74	58	36	60	59	49	68	62
16	77	59	33	61	54	49	58	66
17	66	66	36	61	66	48	59	63
18	65	77	39	60	64	55	55	64
19	80	66	40	58	58	50	56	59
20	77	69	41	55	61	55	58	58
21	63	71	36	58	62	65	58	56
22	67	77	41	59	59	60	59	60
23	66	72	44	61	55	59	60	61
24	65	68	41	62	58	58	66	62
25	59	66	45	66	57	57	57	59
26	70	65	50	60	66	56	54	58
27	64	77	46	66	64	58	58	58
28	66	74	25	65	63	64	61	60
29	80	78	35	67	63	62	62	65
30	71	77	30	70	60	58	58	58
31	70	74	33	71	64	50	57	59
32	65	66	36	65	61	55	62	57
33	66	60	39	66	65	54	70	54
34	68	60	40	63	63	58	74	62
35	71	63	45	64	66	48	50	60
36	72	62	44	68	58	40	55	58
37	64	65	46	66	54	45	58	59
38	69	70	48	61	55	48	59	60

	PF	SF	PRL	ERL	MH	E/F	PAIN	GHP
39	68	77	44	50	58	49	66	64
40	63	66	46	55	57	51	65	59
41	65	71	49	58	55	54	64	57
42	59	63	30	54	56	51	59	57
43	69	69	25	59	63	52	58	69
44	77	67	25	60	66	48	57	60
45	75	71	30	66	62	45	58	61
46	60	70	33	64	59	50	59	66
47	72	62	36	58	59	51	66	60
48	64	62	33	59	58	46	59	59

PF = physical function, SF = social function, PRL = physical role limitation, ERL = emotional role limitation, MH = mental health, E/F = energy/ fatigue, GHP = general health perception. The first column records the individual patients who are assigned a number, 1 to 48.

BASELINE QUALITY OF LIFE SCORES
FEMASSIST GROUP
KINGS HEALTH QUESTIONNAIRE

The baseline Kings Health Questionnaire quality of life scores for women randomised to use the FemAssist device (n=53) are illustrated below.

	GHP	Inimp	EL	RL	SL	S/E	PersL	Physl	SM
1	0	66.6	11.1	16.6	0	33.3	0	33.3	33.3
2	25	100	22.2	16.6	11.1	33.3	0	33.3	50
3	51	0	100	66.6	33.3	33.3	50	66.6	66.6
4	25	33.3	40	16.6	33.3	0	0	25	33.3
5	25	100	88.8	66.6	55.5	16.6	33.3	83.3	66.6
6	0	66.6	44.4	16.6	11.1	33.3	50	33.3	60
7	50	66.6	33.3	66.6	55.5	16.6	33.3	66.6	50
8	25	100	22.2	0	11.1	50	0	16.6	40
9	25	66.6	22.2	33.3	22.2	50	16.6	50	60
10	50	100	0	33.3	0	50	0	50	26
11	0	66.6	11.1	33.3	22.2	0	33.3	66.6	33.3
12	25	66.6	44.4	33.3	0	83.3	0	50	40
13	50	66.6	0	33.3	40	0	0	33.3	33.3
14	0	100	33.3	50	11.1	0	0	33.3	50
15	50	100	100	100	55.5	50	83.3	66.6	66.6
16	50	66.6	44.4	66.6	66.6	33.3	100	66.6	80
17	20	100	88.8	83	44.4	50	16.6	100	66.6
18	75	100	100	66.6	100	66.6	100	100	73.3
19	33.3	66.6	0	0	25	0	33.3	33.3	50
20	50	66.6	66.6	33.3	0	66.6	33.3	50	33.3
21	25	33.3	33.3	33.3	0	33.3	16.6	16.6	60
22	75	100	77.7	66.6	100	83.3	100	83.3	73.3
23	25	100	55.5	66.6	44.4	33.3	0	66.6	33.3
24	25	66.6	33.3	66.6	44.4	33.3	33.3	83.3	66.6
25	75	100	0	83	33.3	0	0	66.6	80
26	50	100	100	16.6	100	16.6	0	100	73.3
27	0	66.6	22.2	16.6	0	33.3	0	16.6	40
28	25	66.6	22.2	33.3	11.1	50	0	66.6	66.6
29	25	100	55.5	33.3	33.3	0	0	50	53.3
30	50	66.6	11.1	66.6	33.3	0	0	50	33.3
31	50	33.3	22.2	0	0	83.3	0	0	53.3
32	0	66.6	33.3	33.3	22.2	0	33.3	33.3	20
33	66.6	66.6	0	33.3	33.3	0	0	33.3	33.3
34	25	66.6	55.5	66.6	22.2	50	0	66.6	26.6
35	0	66.6	11.1	0	0	16.6	0	50	6.6
36	25	100	22.2	66.6	22.2	0	0	50	33.3
37	50	100	22.2	66.6	44.4	0	66.6	83.3	80
38	66.6	33.3	25	25	0	0	33.3	33.3	25

	GHP	Inimp	EL	RL	SL	S/E	PersL	Physl	SM
39	0	33.3	11.1	16.6	22.2	16.6	0	50	26.6
40	25	100	66.6	66.6	66.6	33.3	66.6	66.6	73.3
41	25	100	44.4	66.6	44.4	16.6	33.3	66.6	73.3
42	50	66.6	22.2	0	0	33.3	16.6	50	40
43	25	66.6	44.4	66.6	11.1	0	33.3	66.6	66.6
44	50	100	100	50	55.5	16.6	33.3	83.3	73.3
45	0	66.6	33.3	66.6	44.4	0	33.3	66.6	66.6
46	50	100	11.1	50	22.2	33.3	33.3	66.6	26.6
47	50	100	66.6	66.6	55.5	33.3	66.6	66.6	80
48	0	66.6	33.3	16.6	22.2	16.6	16.6	50	26.6
49	50	66.6	33.3	50	33.3	33.3	16.6	50	50
50	0	50	0	66.6	22.2	16.6	16.6	50	50
51	0	100	40	33.3	33.3	33.3	33.3	66.6	66.6
52	50	50	40	50	22.2	33.3	33.3	50	66.6
53	60	100	66.6	33.3	33.3	16.6	16.6	50	26.6

The first column records the individual patients who are assigned a number, 1 to 53. GHP= General health perception, Inimp= Incontinence impact, EL= Emotional limitation, RL= Role limitation, S/E= Sleep/energy disturbance, PersL= Personal limitation, PhysL= Physical limitation, SL= Social limitation, SM= Severity measures.

BASELINE QUALITY OF LIFE SCORES
FEMASSIST GROUP
UK SHORT FORM 36
HEALTH SURVEY QUESTIONNAIRE

The baseline SF-36 questionnaire quality of life scores for women randomised to use the FemAssist device (n=53) are illustrated below.

	PF	SF	PRL	ERL	MH	E/F	PAIN	GHP
1	66	66	33	66	66	66	80	66
2	66	66	43	66	66	66	66	66
3	66	66	60	66	55	55	60	50
4	55	55	55	55	55	55	66	50
5	55	55	55	55	66	66	55	50
6	77	0	22	77	55	55	55	66
7	66	88	33	77	50	55	77	55
8	66	77	33	66	55	66	66	55
9	66	80	25	66	66	66	66	55
10	6	80	25	55	66	55	55	66
11	55	66	33	55	44	55	66	70
12	55	80	33	66	55	50	55	70
13	70	66	66	66	75	55	55	70
14	77	66	20	55	66	44	66	66
15	66	55	20	55	66	66	66	55
16	66	55	25	66	55	55	55	66
17	77	66	25	66	5	44	45	60
18	70	70	25	55	55	50	45	60
19	88	70	33	55	66	66	45	60
20	77	66	33	66	66	55	55	66
21	66	55	33	66	44	66	70	55
22	66	59	25	50	58	55	70	55
23	55	55	25	50	6	50	66	55
24	55	66	44	50	66	50	50	60
25	55	70	44	55	55	50	50	60
26	85	80	55	55	44	66	55	58
27	66	66	55	66	44	66	66	66
28	55	88	33	44	55	60	66	66
29	74	80	33	44	55	55	55	66
30	66	66	25	55	55	60	55	50
31	66	66	25	85	66	66	55	50
32	60	55	33	66	66	66	66	55
33	60	55	45	33	55	55	77	55
34	60	60	44	33	60	44	77	66
35	66	55	55	55	60	44	60	66
36	66	55	55	55	60	44	60	66
37	55	66	66	44	55	54	60	50
38	55	66	55	77	66	54	60	50

	PF	SF	PRL	ERL	MH	E/F	PAIN	GHP
39	70	66	50	55	66	55	55	50
40	77	55	50	66	50	55	55	70
41	66	55	44	55	50	44	60	70
42	66	55	22	66	50	55	60	55
43	70	55	33	66	66	66	55	55
44	66	60	33	55	66	66	55	66
45	55	60	33	55	33	66	55	66
46	55	60	33	66	66	55	66	55
47	78	60	40	55	66	55	55	55
48	66	60	40	55	55	33	55	66
49	66	66	40	66	66	55	66	66
50	70	66	40	66	66	66	50	66
51	70	55	33	55	55	55	66	70
52	66	55	40	55	60	55	66	55
53	55	70	40	66	50	50	50	55

PF = physical function, SF = social function, PRL = physical role limitation, ERL = emotional role limitation, MH = mental health, E/F = energy/ fatigue, GHP = general health perception. The first column records the individual patients who are assigned a number, 1 to 53.

QUALITY OF LIFE SCORES AFTER TREATMENT
RELIANCE GROUP
KINGS HEALTH QUESTIONNAIRE

The Kings Health Questionnaire quality of life scores for women obtained following utilisation of the Reliance device (n=31) are illustrated below. The first column records the individual patients who are assigned a number, 1 to 48.

	GHP	Inimp	EL	RL	SL	S/E	PersL	Physl	SM
1	0	0	0	0	0	33.3	0	16.6	14.6
2	25	33.3	22.2	16.6	11.1	33.3	0	33.3	25
5	25	33.3	77.7	33.3	44.4	33.3	33.3	33.3	25
7	50	33.3	33.3	33.3	33.3	0	33.3	33.3	25
9	25	33.3	22.2	33.3	0	33.3	16.6	16.6	20
12	25	33.3	22.2	16.6	0	66.6	0	16.6	13.3
14	0	33.3	16.6	16.6	0	33.3	0	16.6	0
15	50	66.6	100	83.3	55.5	66.6	83.3	66.6	53.3
16	50	33.3	33.3	33.3	22.2	33.3	33.3	33.3	20
17	25	66.6	88.8	50	11.1	33.3	16.6	33.3	25
18	50	33.3	33.3	33.3	33.3	33.3	33.3	16.6	60
19	33.3	50	0	0	25	0	33.3	33.3	33.3
21	25	33.3	33.3	33.3	0	33.3	16.6	16.6	40
22	75	66.6	77.7	33.3	77.7	83.3	83.3	33.3	53.3
23	0	33.3	44.4	50	22.2	0		33.3	80
24	25	33.3	33.3	33.3	33.3	33.3	16.6	33.3	26.6
25	25	33.3	0	33.3	22.2	0	00	33.3	33.3
27	25	66.6	11.1	16.6	22.2	33	33.3	33.3	13.3
29	25	66.6	44.4	33.3	0	83.3	33.3	33.3	46.6
30	40	33.3	0	33.3	22.2	0	0	33.3	26.6
32	0	33.3	22.2	33.3	11.1	0	33.3	16.6	6.6
34	25	33.3	33.3	33.3	22.2	33.3	0	33.3	26.6
36	25	33.3	33.3	50	22.2	0	0	33.3	6.6
37	25	66.9	22.2	66.6	22.2	0	33.3	66.6	60
39	0	33.3	11.1	16.6	11.1	16.6	0	16.6	6.6
40	25	33.3	33.3	33.3	33.3	33.3	33.3	0	20
41	75	80	44.4	66.6	44.4	16.6	33.3	66.6	73
42	25	33.3	22.2	0	0	33.3	16.6	16.6	26.6
43	35	33.3	55.6	66.6	33.3	0	66.6	33.3	40
47	45	66.6	100	66.6	88.8	33.3	66.6	100	53.3
48	0	33.3	33.3	0	22.2	16.6	0	16.6	20

GHP= General health perception, Inimp= Incontinence impact, EL= Emotional limitation, RL= Role limitation, S/E= Sleep/energy disturbance, PersL= Personal limitation, PhysL= Physical limitation, SL= Social limitation, SM= Severity measures.

QUALITY OF LIFE SCORES AFTER TREATMENT
RELIANCE GROUP
UK SHORT FORM 36
HEALTH SURVEY QUESTIONNAIRE

The SF-36 questionnaire quality of life scores for women obtained following utilisation of the Reliance device (n=31) are illustrated below. The first column records the individual patients who are assigned a number, 1 to 48.

	PF	SF	PRL	ERL	MH	E/F	PAIN	GHP
1	88	84	65	66	66	52	67	55
2	90	84	66	60	66	66	65	50
5	87	87	80	62	55	56	56	66
7	90	85	65	66	66	62	72	62
9	87	89	66	74	50	62	66	66
12	91	100	69	66	66	55	60	62
14	88	89	69	70	65	55	62	55
15	91	85	66	56	63	46	66	60
16	90	86	64	66	50	52	64	66
17	86	86	69	60	66	49	55	59
18	80	80	62	66	63	60	57	66
19	80	84	67	60	64	56	60	65
21	88	78	84	55	58	61	80	55
22	87	90	68	55	64	65	71	66
23	88	85	69	66	50	55	70	63
24	85	84	67	66	60	52	62	66
25	90	89	70	60	60	60	50	60
27	90	89	77	66	66	55	55	55
29	97	100	63	66	60	61	66	66
30	90	96	64	60	66	66	60	59
32	86	90	89	60	57	57	66	55
34	87	80	80	60	58	62	70	66
36	89	80	61	66	55	43	60	55
37	94	85	60	60	50	46	60	55
39	94	88	64	59	66	44	60	66
40	89	84	59	50	55	54	63	60
41	92	75	61	55	50	52	57	57
42	95	79	60	50	59	46	55	54
43	86	77	66	66	63	50	51	66
47	88	87	69	60	64	50	60	66
48	84	77	64	68	63	49	66	60

PF = physical function, SF = social function, PRL = physical role limitation, ERL = emotional role limitation, MH = mental health, E/F = energy/ fatigue, GHP = general health perception.

QUALITY OF LIFE SCORESAFTER TREATMENT
FEMASSIST GROUP
KINGS HEALTH QUESTIONNAIRE

The Kings Health Questionnaire quality of life scores for women obtained following utilisation of the FemAssist device (n=36) are illustrated below.

	GHP	Inimp	EL	RL	SL	S/E	PersL	Physl	SM
1	0	0	0	0	0	33.3	0	16.6	14.6
3	75	33.3	22.2	16.6	11.1	33.3	0	33.3	25
5	50	66	77.7	33.3	44.4	16.6	33.3	0	25
6	50	33.3	33.3	33.3	33.3	0	33.3	33.3	25
7	50	66	22.2	33.3	0	33.3	16.6	16.6	20
9	25	33.3	22.2	16.6	0	66.6	0	16.6	13.3
10	55	33.3	16.6	33.3	0	33.3	0	16.6	0
11	0	66.6	100	83.3	55.5	0	83.3	16.6	53.3
12	25	33.3	33.3	33.3	22.2	33.3	33.3	33.3	20
13	50	66.6	88.8	66.6	11.1	50	16.6	0	25
14	0	33.3	33.3	33.3	33.3	33.3	33.3	16.6	25
15	50	50	0	66.6	25	0	33.3	33.3	33.3
17	25	33.3	33.3	33.3	0	33.3	16.6	16.6	40
18	50	66.6	77.7	50	66.6	66.6	100	16.6	33.3
20	25	33.3	44.4	33.3	33.3	33.3	0	33.3	20
21	25	33.3	33.3	33.3	33.3	33.3	16.6	16.6	26.6
22	75	66.6	0	33.3	22.2	0	0	16.6	33.3
23	25	66.6	22.2	0	0	33.3	0	0	26.6
24	25	66.6	44.4	33.3	0	33.3	33.3	33.3	46.6
25	25	33.3	0	33.3	22.2	0	0	33.3	26.6
26	0	66.6	22.2	33.3	11.1	0	33.3	33.3	6.6
27	0	33.3	33.3	33.3	22.2	33.3	0	16.6	26.6
28	25	33.3	33.3	50	22.2	0	0	33.3	6.6
29	25	66.6	22.2	66.6	22.2	0	33.3	33.3	60
32	0	33.3	11.1	16.6	11.1	16.6	0	16.6	6.6
33	75	33.3	33.3	33.3	33.3	33.3	33.3	16.6	20
34	25	80	44.4	66.6	33.3	16.6	33.3	0	66.6
36	25	33.3	22.2	33.3	0	33.3	16.6	0	26.6
37	50	33.3	33.3	66.6	33.3	0	66.6	16.6	40
38	50	33.3	44.4	50	22.2	0	0	0	80
39	0	66.6	11.1	66.6	22.2	33.3	33.3	33.3	13.3
40	25	66.6	100	66.6	88.8	33.3	66.6	33.3	53.3
41	25	33.3	33.3	0	22.2	16.6	0	100	20
42	25	66	33.3	85	22.2	0	33.3	16.6	45
44	33.3	75	33.3	66.6	22.2	0	33.3	0	50
47	50	75	33.3	66.6	22.2	16.6	33.3	0	33.3

GHP= General health perception, Inimp= Incontinence impact, EL= Emotional limitation, RL= Role limitation, S/E= Sleep/energy disturbance, PersL= Personal limitation, PhysL= Physical limitation, SL= Social limitation, SM= Severity measures.

QUALITY OF LIFE SCORES AFTER TREATMENT
FEMASSIST GROUP
UK SHORT FORM 36
HEALTH SURVEY QUESTIONNAIRE

The SF-36 questionnaire quality of life scores for women obtained following utilisation of the FemAssist device (n=36) are illustrated below.

	PF	SF	PRL	ERL	MH	E/F	PAIN	GHP
1	77	77	77	55	60	60	60	60
3	80	77	77	55	60	60	60	60
5	80	77	85	66	66	60	60	60
6	80	90	80	60	60	60	66	66
7	80	88	77	60	60	66	66	60
9	88	85	77	55	60	66	66	60
10	77	85	75	55	60	66	60	66
11	77	85	70	66	60	66	66	66
12	88	90	70	66	66	60	60	60
13	80	90	70	66	60	60	60	60
14	88	90	88	58	66	60	60	66
15	88	88	66	58	66	60	60	66
17	80	80	66	60	66	66	77	66
18	80	88	6	60	66	66	75	60
20	80	80	80	60	60	60	60	60
21	66	88	80	66	60	60	60	60
22	77	88	77	66	60	60	60	66
23	90	66	75	60	60	66	60	66
24	88	85	75	60	60	60	60	60
25	85	85	77	66	60	60	66	55
26	88	99	70	66	66	60	60	50
27	90	88	70	66	66	43	60	50
28	88	88	70	66	66	46	66	55
29	77	88	77	66	66	60	66	50
32	88	80	77	66	60	60	66	55
33	88	80	77	60	60	60	63	55
34	88	80	61	60	66	55	60	60
36	90	80	77	60	66	55	60	60
37	90	75	65	60	60	55	55	60
38	90	80	65	66	60	60	50	64
39	80	80	65	60	66	66	62	60
40	88	80	88	66	66	60	66	55
41	90	80	62	66	66	60	66	55
42	88	80	65	60	60	66	60	66
44	90	90	65	60	66	60	66	70
47	88	88	88	66	66	60	62	60

PF = physical function, SF = social function, PRL = physical role limitation, ERL = emotional role limitation, MH = mental health, E/F = energy/ fatigue, GHP = general health perception.

DECLARATION

The research contained in this thesis was carried out in the department of Urogynaecology at Kings College Hospital, an associated hospital of the University of London, under the supervision of Professor Linda Cardozo. The thesis is based upon original experiments and observations performed by me, including the follow-up of patients and the urodynamic investigations. These studies have full ethical approval granted by the Medical Ethics Committee of Kings College School of Medicine and Dentistry. All the databases were compiled by me and I carried out all the analyses on the acquired data.

ACKNOWLEDGEMENTS

Linda Cardozo is an exceptionally gifted academic and clinician and I am privileged to count her as my mentor. Her insistence on the highest standards in all aspects of research and constant review of this thesis was beyond measure, and for this I thank her.

I wish to express my thanks to Philip Toozs-Hobson and Andrew Hextall, other researchers in the unit, for their help in recruiting women to the trial. I am especially grateful to Sister Kate Anders who has contributed greatly to the practical applications and feasibility of the experiments.

I am particularly thankful to Mr Con Kelleher and Mr Vic Khullar who designed the Kings Health Questionnaire, which I have used in this research. They offered me useful advise, together with support and encouragement, at the beginning of the project. I am indebted to Ken Allen and the Department of Medical Physics who modified and maintained the urodynamic equipment used.

This thesis is dedicated to my wife Maeve, for her infinite strength and loyalty.